DESIGN-BUILD

AGREEMENT

between

Oregon State University (OSU)

(Owner)

and

_____

(Design-Builder)

Dated _____, 20___

DESIGN-BUILD AGREEMENT

THIS DESIGN-BUILD AGREEMENT (this "Agreement") is made this _____ day of _____, 20___ (the "Effective Date"), by and between Oregon State University (OSU), a public university (the "Owner"), and _____, a[n] _____ (the "Design-Builder") (collectively, the "Parties"). Owner and Design-Builder agree as follows:

ARTICLE 1

DEFINITIONS AND GENERAL PROVISIONS

1.1 Definitions. The following terms have the meanings set forth below:

"Alternate" shall mean a scope of work that Design-Builder shall include in applicable budgets and estimates, such that Owner may, at its option and in its sole discretion, approve or disapprove the same as an additional component of the Work.

"Alternate Schedule" shall mean Design-Builder's separate and identifiable pricing and scheduling information for all Alternates of a Deliverable Portion of Work, including in the applicable Pricing Amendment Documents, for possible addition to the Work.

"BIM" shall mean building information modeling, a design and construction modeling process, that shall be implemented during design and construction of the Project.

"BIM Model" shall mean the digital model or models produced during the design and construction of the Project.

"Bridging Documents" shall mean the Owner's design documents illustrating and identifying the framework of a Deliverable Portion of Work's design, including functional, aesthetic, and quality requirements.

"Business Inclusion and Diversity Program" shall have the meaning given in the General Conditions.

"Claim" shall have the meaning given in the General Conditions.

"Construction Contingency" shall mean separately identifiable contingency funds included in a Pricing Amendment as set forth in *Section 7.4* of this Agreement.

"Construction Documents" shall mean the documents Design-Builder and its consultants prepare for use when performing construction of a Deliverable Portion of Work, or the Project, as the context requires.

"Construction Phase" shall mean the phase of a Deliverable Portion of Work after Owner and Design-Builder enter into a Pricing Amendment for that Deliverable Portion of Work.

"Construction Schedule" shall have the meaning given in the General Conditions.

"Constructor's Standard of Care" shall mean the professional standard that prevails in comparable areas throughout the United States among construction professionals and construction firms experienced with, and performing the construction and management of, projects similar to the scope, quality, and complexity of the Project.

"Contract Documents" shall have the meaning given in the General Conditions.

"Day" shall have the meaning given in the General Conditions.

"Deliverable Portion of Work" shall have the meaning given in the General Conditions.

"Design Phase" shall mean the phase of a Deliverable Portion of Work prior to Owner and Design-Builder entering into a Pricing Amendment for that Deliverable Portion of Work.

"Design Professional" shall mean [_____] or other professional organization that Design-Builder engages to perform Services, acting in accordance with ORS Chapter 671 (Architects) or ORS Chapter 672 (Engineers) and administrative rules adopted pursuant to the same.

"Design Professional's Standard of Care" shall mean the professional standard that prevails in comparable areas throughout the United States among design professionals and design professional firms experienced with, and performing the design and administration of, projects similar to the scope, quality, and complexity of the Project.

"Design Schedule" shall mean Design-Builder's comprehensive, detailed, updated, schedule for delivery of the Services of a Deliverable Portion of Work that is consistent with the Project Schedule, and approved by Owner in writing.

"Early Work" shall mean Work, including preparatory activities and long lead time materials, Design-Builder shall perform under an Early Work Amendment (defined below) prior to a Pricing Amendment that includes such Work.

"Early Work Amendment" shall mean Owner's written order describing and authorizing Design-Builder to proceed with certain Early Work in a form substantially similar to attached *Exhibit B*.

"Estimated Pricing Amendment Sum" shall mean Design-Builder's estimate of the total cost to Owner of a Deliverable Portion of Work.

"Estimated Project Sum" shall mean Design-Builder's preliminary estimate of the total amount Owner will pay for the Project, generated in accordance with *Section 5.2*.

"Final Completion" shall have the meaning given in the General Conditions.

"General Conditions" shall mean the General Conditions of the Contract for Construction attached as *Exhibit A*.

"Guaranteed Substantial Completion Date" shall mean the date, as set forth in the applicable Pricing Amendment, by which Design-Builder shall achieve Substantial Completion of the applicable Deliverable Portion of Work.

"Instruments of Service" shall mean the Drawings, Specifications, and other documents and information expressing the Project, whether in form, function, concept, or otherwise, produced by Design-Builder or its Subcontractors.

"Key Personnel" shall have the meaning given in *Section 4.5* of this Agreement.

"Liquidated Damages" shall have the meaning given in *Section 8.3* of this Agreement.

"Notice to Proceed" shall have the meaning given in the General Conditions.

"Owner Parties" shall mean, individually or collectively, as the case may be, Owner, Owner's Representative, and Design Professional provided, however, Owner shall have the exclusive right to change at any time such parties so designated as Owner Parties.

"Owner-Supplied Equipment and Materials" shall mean equipment and materials Owner procures and supplies for Design-Builder's incorporation in the Project as part of the Work.

"Owner's Representative" shall mean _____, or its successor as designated by Owner, to whom Owner has delegated some or all of Owner's Project duties and responsibilities.

"Preliminary Services Sum" shall mean the lump sum amount payable by Owner to Design-Builder for Services rendered before Owner agrees to a Pricing Amendment applicable to those Services.

"Pricing Amendment" shall mean an amendment to this Agreement, signed by Owner and Design-Builder, determined in accordance with *Article 5*, issued in the form of *Exhibit C*, establishing the Pricing Amendment Sum, compensation method, Guaranteed Substantial Completion Date as updated and set forth in the Project Schedule, and Pricing Amendment Documents, for each Deliverable Portion of Work.

"Pricing Amendment Documents" shall mean the Drawings, Specifications, clarifications, qualifications, assumptions, and other documents, upon which a Pricing Amendment is based, all as approved by Owner.

"Pricing Amendment Sum" shall mean the maximum amount payable by Owner to Design-Builder for a Deliverable Portion of Work.

"Project Criteria" shall mean Owner's preliminary Project information, which may include preliminary designs, design requirements, programming information, Bridging Documents, physical characteristic requirements, sustainable objectives, siting requirements, geotechnical reports or data, preliminary budget, scheduling information and milestone dates, or other requirements and information, all as set forth in *Exhibit D*, as the same may be supplemented from time to time, subject to the Project Schedule.

"Reimbursable Expenses" shall mean Design-Builder's consultants' (including Design Professional) travel and subsistence expenses, communication services, approval fees of authorities have jurisdiction over the Services, document production fees, postage and shipping fees, Site office expenses, and other similar Owner-approved Project-related expenses.

"Services" shall mean the design services Contractor furnishes to fulfill its Project obligations and execute the terms of the Contract Documents.

"Standard of Care" shall mean Design Professional's Standard of Care, or Constructor's Standard of Care, as the context requires.

"Supporting Documents" shall have the meaning given in the General Conditions.

"Work" shall have the meaning given in the General Conditions.

1.2 Other Terms. In addition to the terms defined in this *Article 1*, other terms are defined throughout this Agreement in sections relevant to their use, and in the General Conditions. If terms are not defined in this Agreement or the General Conditions, they shall have their well-known technical or construction industry meanings.

1.3 Context. As the context of each provision of this Agreement changes, so too shall its verbs and nouns. Specifically, terms in the singular and the plural shall include one another, and terms in the feminine, masculine, or neuter, shall include one another. Use of the word "including" throughout this Agreement shall mean "including without limitation" and shall not be deemed a limitation but instead an illustration.

1.4 Incorporation by Reference. All exhibits, schedules, and other attachments to this Agreement, including the General Conditions, shall be incorporated in and integral to this Agreement by their reference.

1.5 General Conditions. Design-Builder is referred to in the General Conditions as "Contractor."

ARTICLE 2

RELATIONSHIP OF THE PARTIES

2.1 Relationship of the Parties. Design-Builder acknowledges and accepts that by the terms of the Contract Documents, Owner places its trust and confidence in Design-Builder. As such, Design-

Builder covenants to: (i) cooperate with Owner Parties; (ii) exercise its best skill and judgment in furthering Owner's interests for the benefit of the Project, including delivering efficient design, construction, administration, management, and supervision; (iii) furnish at all times an adequate supply of labor and Materials; and (iv) perform the Work in conformance with the Contract Documents and in an expeditious and economical manner.

2.2 Open Communication. Design-Builder shall regularly communicate with Owner Parties for the duration of the Project.

ARTICLE 3

OWNER'S RIGHTS AND RESPONSIBILITIES

3.1 Timely Response. Owner Parties shall render decisions in a timely manner to avoid unreasonable delay in the orderly progress of the Work; provided, however, Design-Builder shall timely advise Owner Parties of the time requirements pertaining to such decisions.

3.2 Owner's Personnel.

3.2.1 Project Consultants. Owner has separate agreements with Owner's Representative and Owner's other Project consultants, and although referred to in, are not parties to, this Agreement. Owner reserves the right to change Owner's Representative and will give Design-Builder prompt written notice of any such change. None of Owner's Representative's services supplant or modify any of Design-Builder's obligations, whether express, implied, or customary.

3.2.2 Communications. Owner's Representative shall give Design-Builder written direction on behalf of Owner. Unless specifically authorized, Design-Builder shall communicate with Owner, through Owner's Representative. All communications to and from Subcontractors and Suppliers shall be through Design-Builder.

3.2.3 Control. Owner Parties shall not be deemed to have control or charge of, and will not be responsible for acts or omissions of, Design-Builder, Subcontractors, or their respective agents or employees, or any other Persons performing Work.

ARTICLE 4

DESIGN-BUILDER'S RIGHTS AND RESPONSIBILITIES

4.1 Standard of Care. Design-Builder covenants it and its Subcontractors will perform the Work in accordance with the recognized standards of design and construction industry practices. Design-Builder further covenants the Services will be performed in accordance with Design Professional's Standard of Care and Work other than the Services will be performed in accordance with Constructor's Standard of Care.

4.2 Design-Builder's Role Generally. Design-Builder shall fully, properly, and timely, perform all Work, as required by the Contract Documents, to furnish Owner with a first-class, complete, fully-functional Project, capable of being used for its intended purpose. Throughout the Project, Design-Builder shall coordinate and manage the design and building process as an independent contractor, continuously monitor the schedules and budgets pertaining to the Work, and recommend adjustments to the Project as necessary to ensure completion of the Project in the most expeditious and efficient manner possible. During the Construction phase, Design-Builder shall be the Project's general contractor.

4.3 Cooperation. Design-Builder covenants to support a collaborative and cooperative relationship among it, Owner, Owner's Representative, Design Professional, other Project participants, and others Owner may engage to perform services or work not included in the Work. Design-Builder

shall obtain and transfer, or assist others to obtain and transfer, warranties, and to perform warranty and inspection Work for the Project through the expiration date of the applicable warranty period.

4.4 Progress Reports. Design-Builder shall keep Owner Parties informed of the progress of the Work. Design-Builder shall submit to Owner Parties monthly Progress Reports, which shall include: (i) Work completed for the reporting period; (ii) an updated Project Schedule, Design Schedule and Construction Schedule, as applicable; (iii) an updated Submittal log including a summary of outstanding Submittals; (iv) pending and approved changes under *Article 10* of the General Conditions; (v) test and inspection reports; and (vi) current total Reimbursable Expenses.

4.5 Design-Builder's Personnel and Consultants.

4.5.1 Design-Builder's personnel shall include those described in Design-Builder's staff chart in attached *Exhibit E* (the "Key Personnel"). Design-Builder shall submit to Owner Parties for approval within fifteen (15) Days of the Effective Date a list of the Key Personnel, which shall include the background, experience, and qualifications, of each of the Key Personnel. Following Owner Parties' approval, Design-Builder shall use best efforts to keep the Key Personnel assigned to the Project and performing in accordance with Owner's expectations and shall not assign to the Project any other senior personnel without Owner Parties' prior written approval.

4.5.2 Design-Builder shall promptly replace any personnel assigned to the Work upon Owner Parties' reasonable objection to such personnel.

4.5.3 In addition to the staff chart referenced above, Design-Builder shall include in *Exhibit E* its individual scheduled payment rates for all Key Personnel and Project personnel. Such rates shall include the pro rata portion of the cost of (a) mandatory and customary contributions and benefits pursuant to Design-Builder's company-wide policy and (b) applicable collective bargaining agreements.

4.5.4 In the event Design-Builder no longer employs any of the Key Personnel, Design-Builder shall promptly notify Owner Parties and shall use best efforts to provide a permanent replacement suitable to Owner Parties within ten (10) Days after such event.

4.5.5 Design-Builder represents that all persons under its direction performing Work who are required by Applicable Laws to be licensed are so licensed and will remain licensed for the duration of the Agreement.

4.6 Governmental Approvals. Design-Builder and Subcontractors shall secure and assist Owner to secure all Governmental Approvals.

4.7 Service Plan.

4.7.1 Submittal. Design-Builder shall submit to Owner Parties for review, within fifteen (15) Days of the Effective Date, its Project service plan. The service plan shall clearly communicate to Owner Parties Design-Builder's Project management plan including Project staffing and a Work Plan, all as set forth below.

4.7.2 Forms and Procedures. Owner Parties may develop forms and procedures for the administration and tracking of the Work and the Contract Documents. Design-Builder agrees it shall incorporate into its service plan all such forms and procedures as Owner Parties may require.

4.7.3 Project Staffing. Design-Builder shall include in its service plan a detailed staffing plan describing Design-Builder's and its consultants' services, including those of the Key Personnel. The staffing plan shall include, at a minimum, (i) the names of all individuals assigned to each Project phase; (ii) a brief description of such individuals' Project roles and responsibilities; and (iii) anticipated percentage of working time such individuals will expend performing Work for each Project phase.

4.7.4 Work Plan. Design-Builder shall include in its service plan and shall implement throughout the Project an updated and comprehensive work plan defining and describing Design-

Builder's (and its Subcontractors' and consultants') deliverables and tasks throughout the design and construction process for each Deliverable Portion of Work, as well as procedures, schedules, documentation, and quality control plans (collectively, the "Work Plan"). The Work Plan shall also include Design-Builder's points of contact, file type and data transfer methods, and other protocols for everyday communications and document processing during preconstruction, construction, and post-construction.

4.8 Owner-Supplied Goods.

4.8.1 Design-Builder acknowledges Owner may supply the Project certain Owner-Supplied Equipment and Materials. Design-Builder shall cooperate with Owner Parties and shall provide information and assistance as Owner Parties may reasonably request to investigate such Owner-Supplied Equipment and Materials. Design-Builder's assistance may include providing quotes or Alternates such that Owner Parties may understand the cost of potential Owner-Supplied Equipment and Materials versus the cost of those same goods supplied through Design-Builder.

4.8.2 If Owner elects to procure Owner-Supplied Equipment and Materials for the Project, Owner Parties, together with Design-Builder, will develop an agreed upon responsibility matrix for the same. However, unless Owner and Design-Builder otherwise agree in writing, the Work shall include coordination, handling, inspecting, preparing, installing, commissioning, and testing such Owner-Supplied Equipment and Materials.

4.8.3 Owner and Design-Builder agree they will sign amendments and other documentation necessary to memorialize their agreement to matters related to the Owner-Supplied Equipment and Materials.

4.9 Building Information Modeling.

4.9.1 Protocols. Design-Builder shall employ BIM to design, engineer, and construct, the Project.

.1 Owner Parties and Design-Builder shall meet to establish written protocols governing the BIM Model (the "BIM Protocols") including file formats, levels of development, authorized uses, and development and safekeeping responsibilities, governing all parties developing the Project's BIM Models. When completed, the BIM Protocols shall govern all parties' development of the Project's BIM Models.

.2 Design-Builder shall be responsible for management, development, and hosting of its BIM Model, its Subcontractors' BIM Models, and the Project's integrated BIM Model. Design-Builder shall have ultimate responsibility to perform clash detection among all BIM Models during the Design Phase and through Final Completion of the Project.

.3 Among Design-Builder's As-Built Documents due prior to Final Completion of each Deliverable Portion of Work, Design-Builder shall deliver to Owner an as-built BIM Model, built from its construction BIM Model, suitable for Owner's continued use during the lifecycle of that completed Work.

4.9.2 Ownership of BIM Models. Owner shall own at all times all of the Project's BIM Models. All parties modeling or otherwise submitting Project-specific data for modeling hereby transfer and convey to Owner all right, title, and interest, in and to, all such data and modeling and to the BIM Models.

4.10 LEED Standards. Design-Builder agrees to use best efforts, including providing all reasonable documentation, to aid Owner Parties in causing the applicable Work to incorporate, within the applicable Pricing Amendment Sum, elements and criteria necessary to qualify for U.S. Green Building Council Leadership in Energy and Environmental Design (LEED) certification points required to achieve

Owner's selected LEED certification standard identified in the Project Criteria (the "LEED Certification Standard"). Design-Builder acknowledges the LEED Certification Standard might include waste and air quality management practices that will directly affect Design-Builder's Site operations.

4.11 Other Obligations. Design-Builder shall perform all other obligations and provide all other services (a) set forth in the Contract Documents and (b) necessary to fully and properly complete the Work.

4.12 Limitation of Authority. Design-Builder shall have no authority to bind Owner without Owner's prior written approval. Design-Builder shall have authority to act on Owner's behalf only to the extent provided in the Contract Documents.

ARTICLE 5

DESIGN PHASE SERVICES

5.1 Design Phase Services. During the Design Phase, Design-Builder shall provide Services, as set forth in this Agreement, including this *Article 5*, and as Owner Parties may reasonably request.

5.2 Project Planning. Design-Builder shall jointly with Owner Parties schedule and attend regular meetings to consult, advise, and solicit feedback from Owner Parties on all aspects of the planning and design of the Project. Design-Builder shall review and comment on Owner's Project Criteria, each in terms of the other. Design-Builder shall assist Owner to refine its proposed budgets, including by generating and delivering to Owner Parties its Estimated Project Sum, utilizing the Project Criteria, and estimating techniques appropriate to the Project's stage of development, and shall refine the Estimated Project Sum based on changes during the Project.

Design-Builder shall schedule and conduct weekly meetings with Owner Parties to review development of the Services, Drawings, Specifications, and the Project in general, including procedures, progress, coordination, and scheduling.

5.3 Project Criteria.

5.3.1 Design-Builder shall meet with Owner Parties to discuss its preliminary evaluation of the Project Criteria (the "Preliminary Evaluation Meeting") during which Design-Builder shall address (a) possible alternative approaches to design and construction of the Project and recommend when appropriate accelerated or fast-track scheduling, procurement, or phased construction and (b) cost information, constructability, and procurement and Project scheduling issues.

5.3.2 Within ten (10) Days of the Preliminary Evaluation Meeting, Design-Builder shall report in writing to Owner Parties with a summary of its understanding and a plan for implementation of the Project Criteria (the "Preliminary Design Report"), including: (i) a preliminary Estimated Project Sum and recommendations for meeting or adjusting the Project Criteria to conform to the Owner's budget; (ii) preliminary Design Schedules, including proposed design milestones; (iii) dates by which information and decisions from Owner are required; (iv) an anticipated date of delivery to Owner Parties of each Pricing Amendment; and (v) dates of periodic design review sessions with Owner Parties; and (vi) programming analysis and diagrams, allocating and detailing program functions' spatial requirements.

5.3.3 Owner Parties shall review the Preliminary Design Report and either approve in writing of, or comment on, the same. Design-Builder shall revise the Preliminary Design Report in accordance with Owner Parties' comments until Owner approves in writing the Preliminary Design Report (the "Preliminary Report Approval"). Upon issuance of the Preliminary Report Approval, Design-Builder shall proceed with the Design Phase in accordance with the Design Schedules; provided, however, the Preliminary Report Approval shall not be deemed to modify the Project Criteria unless

Owner and Design-Builder formally enter into a change in accordance with *Article 10* of the General Conditions.

5.3.4 Design-Builder shall confirm that the Project Criteria complies with Applicable Laws and lawful orders of Governmental Authorities. In the event the Project Criteria conflicts with Applicable Laws or lawful orders of Governmental Authorities, Design-Builder shall notify Owner of the same. If Design-Builder determines that Owner Parties' instructions would cause a violation of Applicable Laws or lawful orders of Governmental Authorities, Design-Builder shall promptly notify Owner Parties in writing.

5.3.5 After Owner issues the Project Criteria, if there is a change to the Project Criteria that is other than a minor change as set forth in *Section 10.3* of the General Conditions, Owner and the Design-Builder shall enter into a Change Order in accordance with *Section 10.3.2* of the General Conditions.

5.4 Project Scheduling.

5.4.1 Preliminary Scheduling. Throughout each Design Phase, Design-Builder shall continue to refine and update the applicable Design Schedule as necessary to respond to changes to the Work.

5.4.2 Project Schedule. Design-Builder shall prepare in conjunction with Owner Parties, and periodically update, a preliminary Project Schedule. Design-Builder shall include the necessary activities and timelines to support the Work of which Design-Builder is aware or believes to be necessary, including off-site transportation, site work outside of the scope of the Work, and off-site utility extensions. Design-Builder and Owner Parties shall each furnish the other with proposed revisions to the preliminary Project Schedule and Design-Builder shall edit and revise the same until Owner approves.

.1 Design-Builder shall be responsible for updating the Project Schedule throughout the duration of the Project.

.2 Design-Builder shall also propose to Owner Parties, and evaluate as requested, alternative schedules for delivery of the Project. Design-Builder shall estimate and inform Owner Parties of affects such alternative schedules may have on the Estimated Project Sum.

5.4.3 Special Procurement Issues. Design-Builder shall investigate and recommend to Owner a schedule for the purchase of Materials and equipment requiring advance procurement (e.g., due to long lead times) and for Owner-Supplied Equipment and Materials. Design-Builder shall also work with Owner Parties to identify critical elements of the Work that may require special procurement.

5.5 Project Phasing. Each Deliverable Portion of Work includes a Design Phase and a Construction Phase. Design-Builder shall recommend to Owner Parties Project phasing and Work prioritization based on the labor and material markets, project logistics, and such other important factors including time of performance, overlapping trade jurisdictions, weather conditions, and provisions for temporary facilities for the Work.

In the event Owner chooses to proceed with the Project or the Work in phases, Design-Builder shall cooperate to economically and efficiently divide the Work into separate Deliverable Portions of Work to accommodate such phases.

5.6 Construction Schedules. Design-Builder shall prepare and update Construction Schedules in accordance with *Section 5.13* below.

5.7 Cost and Constructability. During the Design Phase, Design-Builder shall work with Owner Parties to regularly estimate costs and analyze constructability of all major components and systems of the Work such that the design and budget can timely develop together.

Upon the dates set forth in the Project Schedule and in accordance with the development of the Services, Design-Builder shall submit to Owner Parties its final updated Estimated Project Sum.

5.8 Cost Estimates. Design-Builder shall use the final Estimated Project Sum to prepare for Owner Parties a detailed Project budget, including an Estimated Pricing Amendment Sum for each Deliverable Portion of Work, in accordance with this Agreement, and on the dates set forth in the Project Schedule. Design-Builder shall update its Project budget and Estimated Pricing Amendment Sums, using recognized and accepted industry techniques. In the event the Project's cost estimates, including the Estimated Pricing Amendment Sums, when taken together, exceed the Estimated Project Sum, Design-Builder shall meet with Owner Parties to discuss changes and review alternatives necessary to maintain a mutually acceptable Project budget.

Design-Builder shall estimate the costs of alternative designs or Materials to determine preliminary budgets and their possible economies, including those necessitated by special procurement issues, as set forth in *Section 5.4.3* above.

5.9 Design Documents.

5.9.1 Facilitation of Services. Prior to entering into a Pricing Amendment for a Deliverable Portion of Work, information Design-Builder submits to Owner Parties and Owner's decisions, shall be to facilitate the Services and shall not be deemed to modify the Project Criteria unless Owner and Design-Builder enter into a change in accordance with *Article 10* of the General Conditions.

5.9.2 Design. During the Design Phase, Design-Builder shall advise Owner on proposed Site use and improvements, selection of materials, building systems and equipment, and other pertinent design-related considerations.

5.9.3 Certification. Upon Owner Parties' request, Design-Builder shall furnish Owner Parties with individual certifications from Design Professional and Design-Builder's consultants stating (a) to the best of their knowledge, information and belief, the Drawings, Specifications, or Services to which the certifications relate are (i) consistent with the Contract Documents, except to the extent specifically identified in the certificate, and (ii) comply with Applicable Laws and lawful orders of Governmental Authorities and (b) Owner Parties shall be entitled to rely upon the certification.

5.10 Design Phase Deliverables.

5.10.1 **[**In accordance with the Project Schedule, for each Deliverable Portion of Work, Design-Builder shall prepare and submit to Owner Parties its initial design, including a report identifying any deviations from the Project Criteria, and: (i) a Site plan; (ii) the applicable schematic design; and (iii) updated budgets and pricing estimates (collectively, the "Preliminary Design Deliverable").

5.10.2 Owner Parties shall review the Preliminary Design Deliverable and either approve in writing of, or comment on, the same. Design-Builder shall revise the Preliminary Design Deliverable in accordance with Owner Parties' comments until Owner approves the same in writing. The Preliminary Design Deliverable shall not be deemed to modify the Project Criteria unless Owner and Design-Builder enter into a change in accordance with *Article 10* of the General Conditions.

5.10.3 Upon Owner's approval of the Preliminary Design Deliverable, Design-Builder shall prepare and submit to Owner Parties its final design, including: (i) a report identifying any deviations from the Project Criteria; (ii) developed Drawings and Specifications; and (iii) updated budgets (collectively, the "Final Design Deliverable").

5.10.4 Owner Parties shall review the Final Design Deliverable and either approve in writing of, or comment on, the same. Design-Builder shall revise the Final Design Deliverable in accordance with Owner Parties' comments until Owner approves the same in writing. The Final Design Deliverable shall not be deemed to modify the Project Criteria unless Owner and Design-Builder enter into a change in accordance with *Article 10* of the General Conditions.**]**

OR

5.10.1 **[**In accordance with the Project Schedule, for each Deliverable Portion of Work, Design-Builder shall prepare and submit to Owner Parties its initial design, including a report identifying any deviations from the Project Criteria, and: (i) final programming drawings; (ii) a Site plan; (iii) building plans, sections and elevations; (iv) structural system schematic plans; (v) selection of major building systems, including mechanical, electrical and plumbing systems; (vi) outline specifications describing construction materials; and (vii) updated budgets and pricing estimates (collectively, the "Final Design Deliverable").

5.10.2 Owner Parties shall review the Final Design Deliverable and either approve in writing of, or comment on, the same. Design-Builder shall revise the Final Design Deliverable in accordance with Owner Parties' comments until Owner approves the same in writing. The Final Design Deliverable shall not be deemed to modify the Project Criteria unless Owner and Design-Builder enter into a change in accordance with *Article 10* of the General Conditions.**]**

OR, if using Bridging Services

5.10.1 **[**In accordance with the Project Schedule, for each Deliverable Portion of Work, Design-Builder shall prepare and submit to Owner Parties its initial design, including a report identifying any deviations from the Project Criteria, and, developed from the Bridging Documents: (i) a Site plan; (ii) building plans, sections, elevations, and details; (iii) structural system plans; (iv) building systems plans, including mechanical, electrical and plumbing systems; (v) draft specifications; and (vi) updated budgets and pricing estimates (collectively, the "Final Design Deliverable").

5.10.2 Owner Parties shall review the Final Design Deliverable and either approve in writing of, or comment on, the same. Design-Builder shall revise the Final Design Deliverable in accordance with Owner Parties' comments until Owner approves the same in writing. The Final Design Deliverable shall not be deemed to modify the Project Criteria unless Owner and Design-Builder enter into a change in accordance with *Article 10* of the General Conditions.**]**

5.11 Pricing Amendment. If Owner approves a Final Design Deliverable in accordance with *Section 5.10* above, Design-Builder shall prepare Pricing Amendment Documents, which shall include Work that shall be priced, scheduled, and included in the Contract Documents, as an Alternate, and Work that shall be priced, scheduled, and included in the Contract Documents, as an Allowance. The Alternate Schedule shall include the required start dates for each Alternate, and the sequencing priority of implementing each Alternate.

5.11.1 By including an Allowance in Pricing Amendment Documents, Design-Builder represents and warrants it is a reasonable estimate of the costs of the Work of such Allowance, based on Design-Builder's best skill and judgment, based on the other Pricing Amendment Documents that are sufficiently detailed to make such an estimate. Each Alternate's and Allowance's pricing shall remain valid from the date the applicable Pricing Amendment is fully-signed through the date of Final Completion of the applicable Deliverable Portion of Work containing each such Alternate or Allowance unless, in the case of an Allowance, Design-Builder develops a final price for that portion of the Work included in such Allowance, in which case that final price shall remain valid through the date of Final Completion of the applicable Deliverable Portion of Work.

5.11.2 In accordance with the Project Schedule and based upon the approved Final Design Deliverable and the Estimated Pricing Amendment Sum, Design-Builder shall deliver to Owner Parties for review, comment, and approval its proposed Pricing Amendment, supporting Pricing Amendment Documents, and its Work plan, for the applicable Deliverable Portion of Work.

5.11.3 Upon Owner's approval and the Parties' signatures, a proposed Pricing Amendment shall amend this Agreement, and shall be revised only by Change Order.

5.11.4 Notwithstanding anything to the contrary contained in the Contract Documents, Owner shall not be required to enter into any Pricing Amendment and, unless and until the Parties enter into a Pricing Amendment, Design-Builder's rights, including to payment, under the Contract Documents, shall be limited to only its completed Work, including completed Early Work set forth in an Early Work Amendment.

5.12 Early Work Amendment. Notwithstanding an Early Work Amendment, any Early Work Design-Builder may perform or be authorized to perform shall not waive Owner's right to reject the Pricing Proposal.

5.13 Construction Schedules. Design-Builder shall incorporate the relevant portions of the Project Schedule, into its Construction Schedules. After Owner approves a Pricing Amendment, Design-Builder shall update and distribute with the Progress Report its approved Construction Schedule for that Work. Each such updated Construction Schedule shall conform to the Contract Documents' requirements and shall accurately reflect progress and remaining estimated durations of applicable Work.

5.14 Construction Documents. After Owner and Design-Builder enter into a Pricing Amendment, Design-Builder shall prepare the Construction Documents it will use to construct the Deliverable Portion of Work associated with that Pricing Amendment, which shall be consistent with, and lend further detail to, the Final Design Deliverable.

Upon completion of the Construction Documents, Design-Builder shall provide the same to Owner Parties for review. If Owner Parties discover deviations from the Final Design Deliverable or other inconsistencies among the Construction Documents and the Contract Documents, Owner shall notify Design-Builder in writing of the same. The Construction Documents shall not modify the Project Criteria or the other Contract Documents unless Owner and Design-Builder enter into a change in accordance with *Article 10* of the General Conditions. Owner Parties' failure to discover any such deviations shall not relieve Design-Builder of its obligation to perform the Work in accordance with the Contract Documents.

5.15 Energy Analysis. Design-Builder shall cooperate with Owner Parties and maximize energy efficiency in the Project by proposing, supporting, and estimating costs associated with energy related incentive programs with every construction cost estimate and as Owner Parties may request.

5.16 1% Art Program. Design-Builder shall work with Owner Parties to incorporate into the Project's design and construction works of art from the Project's 1% for Art program. Design-Builder's costs to handle and install such art are properly included in the Contract Sum. However, cost of the included art objects themselves, is not a part of the Contract Sum.

5.17 Other Preparation for Construction. Design-Builder shall plan, in writing and through drawings as appropriate, the Project's Site coordination, including staging and storage areas, and rules applicable to Site operations.

5.17.1 Design-Builder shall recommend a schedule for and, if Owner requests, aid in delivery of, Owner-Supplied Equipment and Materials, including those items requiring special procurement, as set forth in *Section 5.4.3* above.

5.17.2 Design-Builder shall confirm all Construction Documents: (a) coordinate separate Subcontractors' Work, (b) are assigned to the appropriate trade, (c) minimize the likelihood of jurisdictional disputes, and (d) allow for phased construction if and when applicable.

5.17.3 Unless Owner Parties otherwise direct or the Contract Documents otherwise require, Design-Builder shall obtain all permits, licenses, and approvals for the Work, including building, Site development, shoring and excavation, and utilities, as required by Governmental Authorities and customarily obtained by construction contractors.

5.17.4 The Construction Phase of a Deliverable Portion of Work shall not commence prior to a Pricing Amendment for that Work unless and only to the extent set forth in an Early Work Amendment.

ARTICLE 6

CONSTRUCTION PHASE SERVICES

6.1 General Subcontracting Requirements. For purposes of this *Article 6* the term "Subcontractor" shall include the term "Supplier."

Design-Builder shall assure that the Work under all Subcontracts, when taken together, will be complete and sufficient for the entire construction of the Project as required by the Contract Documents.

Design-Builder's Subcontracting records are not intended to be considered public records; provided, however, that Owner and other agencies of the State shall retain the right to audit and monitor the Subcontracting process to protect Owner's interests.

Design-Builder's use of Subcontractors shall not relieve Design-Builder of any of its obligations or liabilities under the Contract Documents. Design-Builder shall have sole responsibility for managing, coordinating, and settling disputes involving any Subcontractor.

6.2 Subcontractor Interest. Design-Builder shall develop Subcontractor interest in the Project and shall furnish Owner Parties with a list of possible Subcontractors for each principal portion of the Work (the "Potential Subcontractor List"). Design-Builder's submission of the Potential Subcontractor List is for information and discussion only and is not for Owner Parties' prequalification. Owner's receipt of the Potential Subcontractor List shall not require Owner Parties to investigate, and shall not waive Owner Parties' right to reject, the qualifications of any Subcontractors.

6.2.1 Design-Builder shall furnish Owner Parties with information and advice concerning current construction market bidding conditions and shall advise Owner Parties of subcontracting opportunities with certified diverse businesses.

6.2.2 Within fourteen (14) Days of Owner and Design-Builder entering into a Pricing Amendment, Design-Builder shall furnish Owner Parties with a written list of proposed Subcontractors for each principal portion of the applicable Work. Owner Parties will reply within seven (7) Days to the Design-Builder in writing if Owner has reasonable objection to any such proposed Subcontractor.

6.2.3 Design-Builder shall comply with OSU Business Inclusion and Diversity Program as set forth in OSU Standard 03-010 and OSU Procurement and Contract Services Manual Section 316.

6.2.4 Design-Builder shall, and require Subcontractors to, comply with State of Oregon Bureau of Labor & Industries prevailing wage rates and the Davison Bacon Act.

6.2.5 Design-Builder shall indemnify, defend, and hold harmless, Owner Parties, from and against any Subcontractor claim that arises due to Design-Builder's failure to incorporate the relevant terms of this *Article 6* and other necessary provisions of the Contract Documents in each Subcontract.

6.2.6 Design-Builder shall, and require Subcontractors to comply with the subcontractor requirements of section 10.3.2.3 of the NIH Policy Statement outlined in Exhibit __.

6.3 Early Work. Design-Builder and Owner may enter into one or more Early Work Amendment identifying specific Work that shall be performed prior to a Pricing Amendment that includes such Work, subject to a not-to-exceed budget and price. All Early Work shall be performed and Owner shall pay for the same in accordance with the terms of the Contract Documents and the terms of the applicable Early Work Amendment.

6.3.1 Prior to commencing any Early Work: (i) Design Professional shall have issued Construction Documents for that Early Work; (ii) Governmental Approvals necessary to commence such Early Work shall have been issued; (iii) Design-Builder shall have submitted, for Owner Parties' review and approval, a Construction Schedule and cost estimate for the Early Work; (iv) Design-Builder shall have selected Subcontractors to perform the Early Work; and (v) Owner Parties shall have issued a Notice to Proceed with the Early Work.

6.3.2 The costs of Early Work shall be included in the applicable Pricing Amendment and Design-Builder's obligation to develop its Pricing Amendments shall not be deferred or waived by any Early Work Amendment.

6.4 Construction.

6.4.1 Scope of Work. Unless otherwise set forth in the Contract Documents, Design-Builder shall provide and pay for labor, Materials, tools, construction equipment and machinery, water, heat, utilities, transportation, and other facilities and services, necessary for proper execution and completion of the Work, whether temporary or permanent, and whether or not incorporated or to be incorporated in the Work.

6.4.2 Substitutions. When a material or system is specified in the Contract Documents, Design-Builder may make substitutions only in accordance with *Article 10* of the General Conditions.

ARTICLE 7

PAYMENT

7.1 Contract Sum. Subject to the terms of the Contract Documents, Owner shall pay Design-Builder the Contract Sum subject to the Preliminary Services Sum and each Pricing Amendment Sum, as the same may be amended from time to time by Change Order. Design-Builder shall bear, without Owner's reimbursement, all costs in excess of (a) the Preliminary Services Sum and (b) each applicable Pricing Amendment Sum.

7.2 Alternates. Owner shall approve each Alternate by Change Order in accordance with *Section 10.3* of the General Conditions. Unless so approved, Design-Builder shall not proceed with an Alternate. If Owner approves one or more Alternates, payment for such approved Alternates shall be included in Design-Builder's applicable Applications for Payment in accordance with *Section 7.5*.

7.3 Allowances.

7.3.1 Design-Builder shall promptly develop and deliver to Owner Parties a final price for each of its Allowances after the Contract Documents pertinent to each such Allowance are completed. If Design-Builder's final price exceeds an Allowance, Owner will elect to: (a) issue a Change Order by an amount to which Owner and Design-Builder agree for the Work of that Allowance, or (b) cause Design-Builder and its consultants to redesign the Work of that Allowance, including Work ancillary to the Work of the Allowance, such that the Allowance price set forth in the applicable Pricing Amendment will not be exceeded.

7.3.2 If Design-Builder's final price is less that an Allowance, Design-Builder and Owner will promptly issue a deductive Change Order to the applicable Pricing Amendment.

7.3.3 In the event some of Design-Builder's final prices exceed, and others are less than, their applicable Allowance prices, Owner may offset such prices to reduce or eliminate the number of Change Orders otherwise necessary due to all of those Allowances.

7.4 Construction Contingency. Each Pricing Amendment shall include a preliminary Construction Contingency in an initial amount to which Owner and Design-Builder agree.

7.4.1 Use of Funds. Subject to Owner Parties' prior written approval, Design-Builder may apply Construction Contingency funds to unexpected increases in costs of the Work, including due to: (i) unforeseen differences in the scope of the Work; (ii) errors in estimating; (iii) overtime expenses; (iv) other errors or omissions not due to breach of the Contract Documents, and not due to negligence or willful misconduct; and (v) Subcontractor default if Design-Builder shows it took reasonable steps to cause each such defaulting Subcontractor or Subcontractor's surety to perform its Work; provided, however, requisite or otherwise available insurance would not cover such default.

In no event shall Construction Contingency funds be used to pay Liquidated Damages.

7.4.2 Reduction Milestones. Each Pricing Amendment's Construction Contingency funds shall not exceed the amounts set forth below upon the milestones set forth below, and the amount of reduction in such funds, if any, shall be credited to Owner by Change Order included with Design-Builder's Application for Payment immediately following each such milestone; unless, however, Owner initiates an additive Change Order allocating any such reductions in Construction Contingency to that Change Order.

Reduction Milestone	**Reduction Amount**
Completion of [**Foundations**]	Construction Contingency funds, not including pending Claims at the time of the milestone, shall not exceed [2.75%] of the applicable Pricing Amendment Sum
Completion of [**Superstructure**]	Construction Contingency funds, not including pending Claims at the time of the milestone, shall not exceed [2.5%] of the applicable Pricing Amendment Sum
Completion of [**Dry-in**]	Construction Contingency funds, not including pending Claims at the time of the milestone, shall not exceed [2.25%] of the applicable Pricing Amendment Sum
Completion of [**Mechanical, Electrical, and Plumbing Rough-in**]	Construction Contingency funds, not including pending Claims at the time of the milestone, shall not exceed [2%] of the applicable Pricing Amendment Sum
[**Five (5)]** days after [**Substantial Completion of the applicable Deliverable Portion of Work**]	Construction Contingency funds, not including pending Claims at the time of the milestone, shall not exceed [1%] of the applicable Pricing Amendment Sum
[**Five (5)**] days after [**Final Completion of the applicable Deliverable Portion of Work**]	Construction Contingency funds, not including pending Claims at the time of the milestone, shall not exceed [0%] of the applicable Pricing Amendment Sum

7.5 Progress Payments.

7.5.1 Applications for Payment.

.1 *Design Services.* Design-Builder shall prepare separate Applications for Payment for the Services of each Deliverable Portion of Work executed, in accordance with *Article 6* of the General Conditions, and this *Section 7.5*. Before an applicable Pricing Amendment Sum is established, Owner shall make progress payments for the Work on account of the Preliminary Services Sum and for documented Reimbursable Expenses. After the applicable Pricing Amendment Sum is established, Owner shall make progress payments on account of that Pricing Amendment Sum as provided in *Article 5* above, including for Reimbursable Expenses.

.2 *Construction Services.* Design-Builder shall prepare separate Applications for Payment for the Work of each Deliverable Portion of Work executed, in accordance with *Article 6* of the General Conditions, and this *Section 7.5*. Owner shall

make progress payments on account of the applicable Pricing Amendment Sum as provided below and elsewhere in the Contract Documents.

7.5.2 Required Contents. Design-Builder shall include the following in each Application for Payment and each shall be a condition precedent to Owner's payment:

.1 *Schedule of Values*. An updated Schedule of Values showing all current expenses pertaining to the Work.

.2 *Percent Complete*. The percentage each portion of the applicable Work is completed, as compared to and categorized in the Schedule of Values, as of the end of the period covered by such Application for Payment. The percentage of the Work that is completed in each Application for Payment shall be the percentage of Work that has actually been completed and not rejected for the applicable Deliverable Portion of Work.

.3 *Progress Report*. A current Progress Report, updated Project, Design, and Construction Schedules, if any, for the Deliverable Portion of Work applicable to the Application for Payment, all in accordance with *Section 4.4* and *Article 5* of this Agreement.

.4 *Supporting Documents*. Supporting Documents and any other evidence Owner Parties reasonably require to demonstrate cash payments, all on account of costs of the Work, equal to or exceeding: (i) progress payments Design-Builder has already received; plus (ii) payrolls for the period covered by the present Application for Payment; plus (iii) retainage as set forth in *Section 7.5.4*, if any, applicable to prior progress payments, less back-charges and credits pursuant to Design-Builder's Subcontracts.

Design-Builder shall include among its Supporting Documents a log of small tool acquisitions along with organized copies of receipts of all small tools purchased for the Project. Design-Builder shall also include in such log records of disposition of small tools whose selling price exceeds one hundred dollars ($100). An up-to-date copy of such log shall accompany each Application for Payment that includes the acquisition or disposition of such small tools.

.5 *Statement of Furnishing*. A sworn statement identifying: (i) the names of all parties furnishing and the goods, labor, or services so furnished to the Project with a value in excess of **[**twenty-five thousand dollars ($25,000)**]** during the time period of the applicable Application for Payment; (ii) payments made to each party furnishing goods, labor, or services; and (iii) amounts due and remaining amounts that are likely to become due to each party furnishing goods, labor, or services.

.6 *Claims Statement*. A statement expressly made to induce Owner's payment, detailing the costs of the Work completed less retainage withheld, along with any Claims pertaining to that Work, sworn to by the Design-Builder and the Subcontractors, attesting to the satisfactory completion of the Work with qualifications pertaining to the Claims.

.7 *Lien and Bond Claim Waivers*. The partial waiver of liens and bond claims, in the form set forth on *Exhibit F*, of Design-Builder and all Subcontractors and their Sub-subcontractors and Suppliers who are listed in the immediately prior Application for Payment for which Design-Builder has received payment.

.8 *No Change Orders*. Design-Builder's statement certifying there are no Change Order requests or other claims for additional payment outstanding, or, if a Change Order request or claim for additional payment is outstanding, the amount of

funds in issue, the name of the potential claimants, and a description of the pertinent Work.

7.5.3 Computation. Subject to other terms of the Contract Documents, progress payments shall be computed as follows:

.1 Take that portion of the applicable cost limitation (i.e., the Preliminary Services Sum or Pricing Amendment Sum) that is properly allocable to completed Work as determined by multiplying the percentage completion of the applicable Work by the share of the cost limitation allocated to that Work in the applicable Schedule of Values. Pending final determination of cost to Owner of changes in the Work, amounts not in dispute may be included.

.2 Add that portion of the applicable cost limitation properly allocable to Materials and equipment delivered, suitably stored, and in compliance with *Section 6.5.3* of the General Conditions.

.3 Subtract the sum of Owner's previous payments made on account of the applicable Work.

.4 Subtract any shortfall indicated in the documentation required by *Section 7.5.2* above to substantiate prior Applications for Payment, or resulting from errors subsequently discovered in such documentation.

.5 Subtract amounts, if any, Owner is entitled to withhold under the Contract Documents.

.6 Subtract retainage in accordance with *Section 7.5.4* below.

7.5.4 Review; Payment; Retainage.

.1 *Submittal*. Each Application for Payment shall cover one calendar month and shall be due on or before the final Day of each month.

On or before the **[25th]** Day of each month, Design-Builder shall submit to Owner Parties a draft Application for Payment, together with all applicable Supporting Documents. Owner Parties will review and comment on the draft Application for Payment and return the same to Design-Builder with comments and changes, if any, within **[**three (3)**]** Days. On or before the **[**final**]** Day of that month, Design-Builder shall submit to Owner Parties its Application for Payment, revised to reflect Owner Parties' comments and changes.

.2 *Payment*. Owner shall pay Design-Builder for the amounts in each approved Application for Payment, delivered pursuant to Owner's invoice delivery requirements, within **[**thirty (30)**]** Days of its receipt of the same. Notwithstanding the foregoing, Design-Builder shall not be entitled to payment unless and until its applicable Application for Payment is approved by all of Owner's reviewing parties. In the event Owner fails to make payment within the time required under this *Section 7.5.4*, Design-Builder shall furnish Owner with **[**ten (10)**]** Days' advance written notice as a condition precedent to exercising remedies, including those available under the Contract Documents. After receiving a payment, within the legal requirement for prompt payment or seven (7) Days, whichever is less, Design-Builder shall pay each Subcontractor amounts due and owing.

.3 *Retainage*. Retainage shall be withheld and released in accordance with this *Section* and *Section 6.7* of the General Conditions. Owner shall retain from all payments to Design-Builder five percent (5%) of each such payment as security for the

Work, until such time as Owner may release retainage or a approves a retainage substitute in accordance with the Contract Documents.

7.6 Final Payment.

7.6.1 Final Application for Payment Accounting. In addition to the requirements set forth in *Sections 6.5* and *6.9* of the General Conditions, Design-Builder shall submit to Owner Parties a detailed final accounting of the Cost of the Work together with its final Application for Payment for each Deliverable Portion of Work. Owner Parties and Owner's agents may review and report to Owner their findings concerning Design-Builder's final accounting (the "Final Accounting Report") within thirty (30) Days after Owner receives such final accounting. Based upon substantiated amounts due, as set forth in the Final Accounting Report, and provided the other conditions of the Contract Documents have been met, Owner Parties will, within seven (7) Days after receiving the Final Accounting Report, make final payment to the Design-Builder.

7.6.2 Computation. Final payment shall be calculated as follows: (i) take the costs of the applicable Work substantiated by the Supporting Documents, less any amount in excess of the applicable Pricing Amendment Sum; (ii) subtract amounts, if any, Owner is entitled to withhold under the Contract Documents; (iii) subtract the amount of any unresolved Claims pertaining to that Work; and (iv) subtract the sum of Owner's previous payments made on account of the applicable Work.

However, notwithstanding the foregoing, if the Final Accounting Report indicates Owner's previous payments made on account of the applicable Deliverable Portion of Work exceed the total amount due Design-Builder for that Work, Design-Builder shall reimburse Owner within thirty (30) Days of such determination with interest at the rate set forth in *Section 14.2* of the General Conditions.

7.6.3 Payment Disputes. In the event Owner Parties determine Design-Builder is due less than amounts requested in its final Application for Payment or Owner otherwise withholds amounts, including because of purported failure of the Work to conform to the Contract Documents' requirements or due to unresolved Claims, and Design-Builder disagrees with any such nonpayment, Design-Builder shall have a Claim in accordance with *Article 12* of the General Conditions.

7.7 Interest. Owner shall pay Contractor interest for payable amounts overdue, which necessarily do not include retainage properly withheld, at the rate set forth in *Section 14.2* of the General Conditions. For purposes of this *Section*, overdue amounts shall be those due and unpaid for not less than forty-five (45) Days from the latest of (a) the date Owner received the accurate, complete, Application for Payment; or (b) the date Owner receives proper notice of a Claim for nonpayment of amounts due and owing.

ARTICLE 8

TIME

8.1 Time is of the Essence. Time is of the essence of this Agreement and of the Contract Documents. Dates and milestones established or shown in the Project Schedule or Construction Schedules shall not be altered except by Change Order.

8.2 Calculation of Time. If a required time period in this Agreement expires on a Day other than a business day, such time period shall be extended to the next succeeding business day.

8.3 Liquidated Damages.

8.3.1 If a Deliverable Portion of Work or other milestone fails to be Substantially Complete until after the Guaranteed Substantial Completion Date applicable to such Work or such milestone for any number of days, Design-Builder shall pay to Owner by offset from the unpaid amount of the Contract Sum or by direct payment, if there remains insufficient unpaid Contract Sum funds to

offset, the per diem liquidated damages amounts set forth in *Exhibit G* for all such days (the "Liquidated Damages"). Liquidated Damages shall be payable upon demand at the time they accrue.

8.3.2 It is understood and agreed by the Parties: (a) Owner will be damaged if Design-Builder fails to meet its obligations under the Contract Documents, including those pertaining to the Project Schedule and Construction Schedules; (b) it will be impracticable or extremely difficult to determine Owner's actual damages resulting from Design-Builder's breach of the Contract Documents, including the Project Schedule and Construction Schedules; and (c) Liquidated Damages payable under this *Article 8* are not a penalty and are instead a fair and reasonable estimate of compensation for the losses that Owner reasonably anticipates under the circumstances of the Project.

8.3.3 Liquidated Damages paid in accordance with this *Article 8* shall be the sole and exclusive measure of damages in the event Design-Builder fails to achieve Substantial Completion of a Deliverable Portion of Work or milestone on or before the Guaranteed Substantial Completion Date for such Work or milestone. However, Liquidated Damages are intended only to cover damages Owner suffers due to delay and do not cover the cost of completion of the Work or other damages, including due to Defective Work.

8.3.4 Construction Contingency shall not be used to pay Liquidated Damages.

8.3.5 This *Section 8.3* shall survive Final Completion and termination of this Agreement.

ARTICLE 9

TERMINATION

8.4 Termination Generally. Any termination of the Contract Documents shall be pursuant to and in accordance with *Article 13* of the General Conditions. In addition to the terms and conditions of *Section 13.2* of the General Conditions, in the event Owner terminates this Agreement for convenience, Design-Builder shall be entitled to payment for only Work performed and accepted up to and including the date of termination, including Reimbursable Expenses, together with amounts payable for completed Early Work for which Owner issued an Early Work Amendment.

ARTICLE 9

MISCELLANEOUS

9.1 Representations and Warranties. Design-Builder represents and warrants to Owner (a) its previously submitted qualifications, references, and financial information were and continue to be true and correct in all material respects and are without material change since the date of their submission and (b) the Contract Documents constitute Design-Builder's legal, valid, and binding obligation, enforceable in accordance with their terms.

9.2 Authority. Design-Builder and Owner each have full power and authority to enter into and perform the Contract Documents and the persons signing this Agreement on behalf of their respective parties are duly authorized to do so.

9.3 Ownership of Documents.

In addition to the terms of the *Section 14.1* of the General Conditions, Design-Builder unconditionally and irrevocably transfers and assigns to Owner for uses connected to the Project an exclusive, royalty-free, license to the Instruments of Service; provided, however, Design-Builder and it Subcontractors shall retain all proprietary and intellectual property rights to the Instruments of Service consistent with the confidentiality provisions of *Section 14.4* of the General Conditions.

9.3.1 Design-Builder shall obtain all necessary releases from Subcontractors to allow it to satisfy its obligations to Owner under this *Article 9*.

9.3.2 In the event Owner alters Instruments of Service without the original author's written authorization or uses the Instruments of Service without retaining the original authors of the Instruments of Service for work other than that which is indicated in those authors' Instruments of Service, the Owner releases such authors from all claims and causes of action arising from or related to such uses. The terms of this *Section 9.3.2* shall not apply if the Owner rightfully terminates this Agreement for cause pursuant to *Section 13.2.4* of the General Conditions.

9.4 **Notice**. Any notice or other written instrument required or permitted pursuant to this Agreement shall be in writing signed by the party giving such notice. Delivery of all such notices and written instruments shall be by hand, overnight courier, or registered letter at the addresses set forth in *Exhibit H*; provided, however, each party shall have the right to change its address by sending notice in the same manner.

9.5 **Third Parties**. Nothing contained in this Agreement shall be deemed to give any third party a claim, Claim, or right of action against Owner or Design-Builder unless that third party is expressly included as an intended beneficiary under the terms of this Agreement.

9.6 **Remedies**. Except as set forth in this Agreement, all rights and remedies contained in this Agreement are in addition to all others available at law or in equity.

9.7 **Headings**. The captions contained in this Agreement are for convenience and reference only and neither extend nor limit the scope or intent of this Agreement or its terms.

9.8 **Exhibits**. All exhibits, schedules, and other attachments referenced in this Agreement are fully incorporated by reference and are an integral part of this Agreement.

9.9 **Entire Agreement**. This Agreement represents the entire and integrated agreement between Owner and Design-Builder and supersedes all prior negotiations, representations, or agreements, whether written or oral. This Agreement may be amended only by written instrument signed by both Owner and Design-Builder.

9.10 **Counterparts**. This Agreement may be signed in separate counterparts, each of which when signed and delivered shall be an original, and all of which when taken together shall constitute one instrument.

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This Agreement is entered into as of the Effective Date.

DESIGN-BUILDER:	**OWNER:**
By: _____	By: _____
Name: _____	Name: _____
Its:	Its:

Exhibit A

GENERAL CONDITIONS

OF THE

CONTRACT FOR DESIGN AND CONSTRUCTION

ARTICLE 1

DEFINITIONS AND GENERAL PROVISIONS

1.1. Definitions. The following terms shall have the meanings set forth below:

"ADA" shall mean the Americans with Disabilities Act of 1990, together with any amendments and rules, regulations, requirements, and best practices promulgated under the authority of the same.

"Addenda" shall mean written, drawn, and graphic instruments and representations issued by Owner Parties prior to Contractor signing the applicable Pricing Amendment that change, clarify, or interpret the Project Criteria.

"ADR Procedures" shall mean the procedures set forth in *Exhibit* __.

"Agreement" shall mean the Design Build Agreement #_____ between Owner and Contractor as the same may be amended from time to time.

"Allowance" shall mean items of Work that Contractor offers to perform at a price that is reasonably estimated but not definitive.

"Applicable Laws" shall mean federal, state and local laws, codes, rules, regulations, zoning and ordinances and university standards and policies applicable to the Project, including: ADA; ORS Chapter 659, as amended; ORS Chapter 659A, as amended; subcontracting laws in ORS 701.005 and ORS Sections 701.021 to 701.068; landscape contractor laws in ORS Sections 671.520(2) and ORS 671.560; excavation notification laws in OAR Sections 952-001-0010 through OAR 952-001-00100; and all regulations and administrative rules established pursuant to the same.

"Application for Payment" shall mean Contractor's certified request for Owner's payment in the form required by the Contract Documents.

"As-Built Documents" shall mean the Drawings and Specifications revised by Contractor to show the as-built condition of the Work and other changes made to the Project during the construction process.

"Avoidable Delay" shall have the meaning given in *Section 7.2.3* of these General Conditions.

"Business Inclusion and Diversity Program" shall mean that program established in OSU Standard 03-010, Procurement Thresholds and Methods, and operated pursuant to the university's Procurement and Contracts unit rules, policies and procedures.

"Certificate for Payment" shall mean each certificate, in the form prescribed in *Section 6.6* of these General Conditions, issued by Owner Parties subsequent to an Application for Payment and in accordance with the Contract Documents evidencing the amount of the Contract Sum then due to Contractor.

"Certified Diverse Business Report" shall mean an accurate report by Contractor delivered to Owner identifying all certified diverse business enterprises certified with the State of Oregon, in accordance with ORS 200.005, performing work associated with the Project. That report is a condition to Final Completion and shall include the total number of contracts and subcontracts awarded to certified diverse business enterprises and the dollar value of each, including all changes during the course of the Project.

"Change Order" shall mean Owner's written order, signed by Owner and Contractor, authorizing and directing a modification to the Contract Documents due to a change to: (i) the scope of the Work, (ii) the Contract Time or a material change to the schedule of performance of the Work or the Project, or (iii) the Contract Sum or Contractor's compensation.

"Claim" shall mean a party to the Contract Document's request, demand, or assertion pertaining to: (i) a material change to the Contract Time or the schedule of performance of the Work or the Project,

(ii) a change to the Contract Sum or Contractor's compensation, (iii) a reasonable dispute concerning conformance with the Contract Documents, (iv) damages suffered directly or indirectly by the act or omission of the other party; or (v) other relief from the terms of the Contract Documents.

"Close-Out" shall mean the process and plan prepared by Contractor that properly prepares the Project for turnover from Contractor to Owner, as set forth in *Section 4.13* of these General Conditions.

"Construction Change Directive" shall mean a written order prepared by Owner Parties and signed by Owner directing Contractor to perform a change in the Work prior to agreeing to a change, if any, to the Contract Time, schedule of performance of the Work, Contract Sum, or Contractor's compensation.

"Construction Contingency" shall have the meaning given in the Agreement.

"Construction Plan" shall mean Contractor's written and graphic plan for performance of the Work for each Deliverable Portion of Work including: (i) Project logistics; (ii) staging, storage, and office areas; (iii) pathways, ingress, and egress on the Site; and (iv) safety plans and managing personnel. [Optional]

"Construction Schedule" shall mean Contractor's comprehensive, detailed, updated, critical path method (CPM) schedule (the "critical path") for each Deliverable Portion of Work, in conformance with accepted industry standards, that is consistent with the Project Schedule, and in a form and format approved in writing by Owner, all as set forth in *Section 4.6.3* of these General Conditions.

"Contract Documents" shall mean, collectively, the Agreement, as amended; these General Conditions, as amended; the Supplemental General Conditions, if any; the Project Schedule, Design Schedules, and Construction Schedule; the Project Criteria and their Addenda; the Pricing Amendments, including the Pricing Amendment Documents; and all approved changes to the Work formalized as minor changes in the Work, Change Orders, and Construction Change Directives.

"Contract Sum" shall mean the total dollar amount payable by Owner to Contractor for the Work of a Deliverable Portion of Work, as set forth in the Agreement.

"Contract Time" shall mean the allotted time to complete the Work of a Deliverable Portion fo Work as set forth in the applicable Construction Schedule.

"Contractor" shall mean the Design-Builder designated in the Agreement, who will manage or perform the Work, and its permitted successors and assigns, or such other design-build firm as Owner may designate from time to time.

"Day" shall mean a calendar day, including weekdays, weekends and holidays, unless otherwise defined.

"Default" shall mean: Contractor's failure to perform the Work in conformance with the Contract Documents; Contractor's failure to supply an adequate number of properly skilled workers or Materials; Contractor's failure to make payments when due and payable for Work or Materials; Contractor's insolvency; commencement of bankruptcy protection by or pertaining to Contractor; Contractor's voluntary bankruptcy action or an involuntary bankruptcy action commenced against Contractor; or Contractor's failure to comply with Applicable Laws.

"Defective Work" shall mean Work that fails to conform to the Contract Documents' requirements.

"Delay" shall mean delays in performance of the Work, the Project, or other execution of the Contract Documents.

"Deliverable Portion of Work" shall mean each portion of the Work, or all Work, as the case may be, that Owner agrees in writing to accept when such Work is Substantially Complete, all as set forth in

the Contract Documents, including the Project Schedule and the Design and Construction Schedule for that Work.

"Design Professional" shall have the meaning given in the Agreement.

"Design Schedule" shall have the meaning given in the Agreement.

"Drawings" shall mean those documents issued to or on behalf of Contractor and approved by Owner showing the design, location and dimensions of the Work, known generally as but not limited to, plans, elevations, sections, details, and schedules.

"Final Completion" shall mean the complete execution of all Contract Documents' requirements for a Deliverable Portion of Work, as the Contract Documents require, including Close-Out as described in *Section 4.13* but excluding warranty Work as described *Section 11.3*, all as described in these General Conditions. The issuance of a final certificate of occupancy for a Deliverable Portion of Work, along with all final approvals from Governmental Authorities, shall be evidence of but not determinative of, Final Completion of that Work.

"Force Majeure" shall have the meaning given in *Section 7.2.2* of these General Conditions.

"General Conditions" shall mean these General Conditions of the Contract for Construction.

"Governmental Approvals" shall mean all permits, licenses, approvals, and consents, of Governmental Authorities required to perform the Work, including performing or approving the Services, or complete the Project.

"Governmental Authority" shall mean any federal, state, county, municipal, local or other governmental body having jurisdiction over approval of Drawings, Specifications, the Work, the Project, or the Site.

"Instruments of Service" shall have the meaning given in the Agreement.

"Liquidated Damages" shall have the meaning given in the Agreement.

"Materials" shall mean all materials, supplies, appliances, equipment, fixtures, and other items that are part of the Work, necessary to complete the Work, or consumed during performance of the Work.

"Notice to Proceed" shall mean official written notice from Owner Parties to Contractor directing Contractor to commence activities described in such notice, including a notice of commencement for all or a portion of the Work.

"Owner Parties" shall have the meaning given in the Agreement.

"Owner's Representative" shall have the meaning given in the Agreement.

"Owner's Separate Contractors" shall mean forces hired by Owner other than Contractor's forces, as set forth in *Section 3.1.5* of these General Conditions.

"Owner's Standard Requirements" shall mean OSU's standard contractor requirements set forth in *Exhibit I*.

"Owner-Supplied Equipment and Materials" shall have the meaning given in the Agreement.

"Person" shall mean any natural person or entity doing business of any kind, including a partnership, a joint venture, a corporation, a limited liability company, and any other entity possessing the legal capacity to contract.

"Product Data" shall mean illustrations, schedules, performance charts, instructions, brochures, diagrams, and other information that Contractor furnishes to illustrate Materials to be incorporated into the Work.

"Progress Report" shall mean Contractor's monthly report to Owner containing an executive summary of completed Work and the contents of the report; the up-to-date Design Schedules and

Construction Schedule; the current actual costs as compared to their budgeted costs for completed activities and estimated costs compared to their budgeted costs for incomplete activities; Construction Contingency status; all known and potential Claims; all material issues relating to the Project that may affect Contract Sum, Contract Time, or Project quality, and proposed solutions for each such issue; status of all outstanding requests for information; current safety and accident report; Project progress photos; and other relevant information reasonably required by Owner.

"Project" shall mean the project described on *Exhibit J* which includes the Work of the Contract Documents.

"Project Schedule" shall mean the overall schedule of the Project, as approved by Owner, including proposed activity sequences and durations, phases and milestone dates, preparation and processing of shop drawings and samples, Owner's occupancy requirements, and pertinent information from Contractor's Design and Construction Schedules, all as updated from time to time.

"Punch List" shall mean the list generated by Contractor and approved by Owner Parties of incomplete or Defective Work that must be corrected before the Project achieves Final Completion.

"Quality Management and Control Plan" shall mean the comprehensive quality management and control plan described in *Section 4.5* of these General Conditions and attached as *Exhibit K*.

"Record Document" shall mean Contractor's As-Built Documents, testing and inspection records, product data, samples, manufacturer and distributor/supplier warranties evidencing transfer of ownership to Owner, operational and maintenance manuals, approved shop drawings, Certified Diverse Business Report, correspondence that is material to the Contract Documents, certificate(s) of occupancy, Close-Out documents, and other documents recording performance of the Work.

"Samples" shall mean physical examples illustrating Materials or workmanship, and shall establish standards upon which the Work will be reviewed and approved.

"Schedule of Values" shall mean Contractor's statement reflecting the portions of the Contract Sum allocated to the various portions of the Work and, when approved by Owner, used as the basis for reviewing and processing Applications for Payment, in accordance with *Section 6.3* of these General Conditions.

"Services" shall have the meaning given in the Agreement.

"Shop Drawings" shall mean drawings, diagrams, schedules, and other data specially prepared for the Work by or on behalf of Contractor to illustrate a portion of the Work.

"Site" shall mean the real property upon which the Work will assembled, located at Sinnhuber Aquatic Research Laboratory (SARL), 28645 East Hwy 34, Corvallis, OR 97333 and further described in *Exhibit L*.

"Specifications" shall mean those documents issued to or on behalf of Contractor and approved by Owner containing the written requirements for Materials, systems, and standards of the Work, including inspection, testing, and warranty requirements.

"Standard of Care" shall have the same meaning as in the Agreement.

"Subcontract" shall mean any agreement between Contractor and a Subcontractor for performance of Work or a Supplier for supplying Materials to the Project.

"Subcontractor" shall mean a Person having an agreement with Contractor to perform Work. Owner's Separate Contractors are not Subcontractors unless Owner expressly assigns them in writing to Contractor.

"Submittals" shall mean any submission to Owner Parties demonstrating how Contractor proposes to conform the Work to the Contract Documents including Shop Drawings, Product Data, Samples, and other customary documents.

"Substantial Completion" and "Substantially Complete" shall mean a Deliverable Portion of Work is sufficiently complete in accordance with the Contract Documents so the Owner can occupy or utilize the same for its intended purpose. In no event shall Work be deemed Substantially Complete unless a certificate of occupancy has been issued for the Project or Deliverable Portion of Work, as the case may be, by the appropriate Governmental Authorities and such Work can be delivered to Owner with only Punch List items unfinished in the common areas that will not interfere with Owner's practical use.

"Substitution" shall mean any product or process Contractor proposes to substitute for one specified in the Contract Documents that completely fulfills the requirements of the Contract Documents and is approved by Owner Parties.

"Sub-subcontractor" shall mean a Person having an agreement with a Subcontractor to perform Work.

"Supplemental General Conditions" shall mean those conditions that remove from, add to, or modify these General Conditions by separate attachment to the Contract Documents.

"Supplier" shall mean a Person having an agreement with Contractor, Subcontractors, or Sub-subcontractors, to supply Materials to the Project.

"Supporting Documents" shall have the meaning given in *Section 6.5.1* of these General Conditions.

"Unavoidable Delay" shall have the meaning given in *Section 7.2.4* of these General Conditions.

"Work" shall mean the furnishing of all Services, Materials, labor, transportation, facilities, management, and other reasonably necessary services and work, to perform and complete design and construction of the Project in accordance with, and reasonably inferable from, the Contract Documents.

1.2. Other Terms. In addition to the terms defined in this *Article 1*, other terms are defined throughout these General Conditions in sections relevant to their use. Terms used but not specifically defined in these General Conditions shall have their well-known technical or industry meanings.

1.3. Context. As the context of each provision of these General Conditions changes, so too shall its verbs and nouns. Specifically, terms in the singular and the plural shall include one another, and terms in the feminine, masculine, or neuter, shall include one another. Use of the word "including" throughout these General Conditions shall mean "including without limitation" and shall not be deemed a limitation but instead an illustration.

1.4. Incorporation by Reference. All exhibits, schedules, and other attachments to these General Conditions shall be incorporated in and integral to these General Conditions by their reference.

1.5. Public Works.

1.5.1 Government Employment Status. If payment under the Agreement will be charged against federal funds, Contractor represents and warrants that it is not currently employed by the Federal Government. This does not preclude Contractor from holding another contract with the Federal Government. Contractor further represents and warrants that Contractor is not an employee of the State of Oregon for purposes of performing Work.

1.5.2 Retirement System Status and Taxes. Contractor represents and warrants that it is not a contributing member of the Oregon Public Employees' Retirement System and will be responsible for any federal or state taxes applicable to payment received under the Contract Documents. Contractor will not be eligible for any federal Social Security, employment insurance, workers' compensation or the Oregon Public Employees' Retirement System benefits from Project payments, except as a self-employed individual. Unless Contractor is subject to backup withholding, Owner will not withhold from its payments to Contractor federal or state tax obligations.

1.5.3 Minimum Wages Rates on Public Works. Contractor shall comply fully with the provisions of ORS Sections 279C.800 through 279C.870. Documents establishing those conditions, as determined by the Oregon Commissioner of the Bureau of Labor and Industries, are included as attachments to or are incorporated by reference in the Contract Documents. Pursuant to ORS 279C.830(1)(c), Contractor shall pay workers not less than the specified minimum hourly rate of wage, and shall include the same minimum hourly rate of wage requirement in all Subcontracts. If the Work is subject to both the Oregon state prevailing wage rate law and the federal Davis-Bacon Act, Contractor shall pay the higher of the two prevailing rates. Contractor shall also provide written notice to all workers of the number of hours per day and days per week such workers may be required to work.

1.5.4 Payroll Certification and Fee Requirements. In accordance with ORS 279C.845, Contractor and every Subcontractor shall submit written certified statements to Owner Parties, on the form prescribed by the Oregon Commissioner of the Bureau of Labor and Industries, certifying the hourly rate of wage paid to each worker that Contractor or a Subcontractor has employed on the project and further certifying that no worker employed on the Project has been paid less than the prevailing rate of wage or less than the minimum hourly rate of wage specified in the Contract Documents. Contractors and Subcontractors shall verify by oath that they have read the certified statement, that they know the contents of the certified statement, and that, to their best knowledge and belief, the certified statement is true. The certified statements shall set out accurately and completely the payroll records for the prior week, including the name and address of each worker, the worker's correct classification, rate of pay, daily and weekly number of hours worked, deductions made, and actual wages paid. Certified statements for each week during which the Contractor or Subcontractor has employed a worker on the project shall be submitted each month, by the fifth business day of the succeeding month. The Contractor and Subcontractors shall preserve their certified statements for a period of ten (10) years from the date of Final Completion.

1.5.5 Additional Retainage. Pursuant to ORS 279C.845(7), Owner shall retain twenty-five (25) percent of any amount earned by Contractor on this public works Project until Contractor has filed the certified statements required by *Section 1.5.4* above. Owner shall pay to Contractor the amount retained under this *Section* within fourteen (14) Days after Contractor files the required certified statements, regardless whether a Subcontractor has failed to file certified statements. Pursuant to ORS 279C.845(8), Contractor shall retain twenty-five percent (25%) of any amount earned by a Subcontractor on this public works Project until that Subcontractor has filed with Owner Parties the certified statements required by *Section 1.5.4* above. Before paying any amount retained under this *Section*, Contractor shall verify that Subcontractor has filed the certified statement. Within fourteen (14) Days after Subcontractor files the required certified statement, Contractor shall pay Subcontractor any amount retained under this *Section*.

1.5.6 Bureau of Labor and Industries Fee. In accordance with statutory requirements and administrative rules promulgated by the Oregon Commissioner of the Bureau of Labor and Industries, the fee required by ORS 279C.825(1) will be paid by Owner to the Commissioner.

1.5.7 Hours of Labor. As a condition to Owner's performance under the Contract Documents, no Person shall be employed to perform Work for more than ten (10) hours in any one Day or forty (40) hours in any one week, except in cases of necessity, emergency, or where public policy absolutely requires it. In such instances, Contractor shall pay the employee at least time and a half pay: (i) for all overtime in excess of eight (8) hours a day or forty (40) hours in any one week when the work week is five consecutive Days, Monday through Friday; (ii) for all overtime in excess of ten (10) hours a day or forty (40) hours in any one week when the work week is four consecutive Days, Monday through Friday; and (iii) for all Work performed on Saturday and on any legal holiday specified in ORS 279C.540. This *Section 1.5.7* will not apply to Contractor's Work to the extent Contractor is currently a party to a collective bargaining agreement with any labor organization as set forth in the Labor

Agreement and shall not excuse Contractor from completion of the Work in accordance with the Construction Schedule and within the Contract Time.

1.5.8 Labor Laws. Contractor shall comply with all applicable requirements of federal and state civil rights and rehabilitation statutes, rules, and regulations. Contractor shall not, in the awarding of Subcontracts, discriminate against businesses that have been certified by the State of Oregon Certification Office for Business Inclusion and Diversity under ORS 200.055. Contractor shall maintain, in current and valid form, all licenses and certificates required by Applicable Laws and by the Contract Documents when performing the Work.

1.5.9 Reserved.

1.5.10 Contractor Certifications. Unless contrary to federal law, Contractor shall certify that it shall not accept a bid to perform Work from Subcontractors as described in ORS 701.005 unless such Subcontractors, if required, are registered with the Oregon Construction Contractors Board in accordance with ORS Sections 701.021 to 701.068 at the time they submit bids. Unless contrary to federal law, Contractor shall certify that each landscape contractor, as defined in ORS 671.520(2), performing Work holds a valid landscape contractor's license issued pursuant to ORS 671.560.

The following notice is applicable to Contractors who perform excavation Work:

> "ATTENTION: Oregon law requires you to follow rules adopted by the Oregon Utility Notification Center. Those rules are set forth in OAR 952-001-0010 through OAR 952-001-00100. You may obtain copies of the rules by calling (503) 232-1987."

1.5.11 Dual Payment Sources. Contractor shall not be compensated for Work from any payment source other than Owner.

ARTICLE 2

CONTRACT ADMINISTRATION

2.1. Correlation of Contract Documents; Execution of Work.

2.1.1 General Meaning. The Contract Documents are complementary. Whatever is called for in one Contract Document, shall be interpreted to be called for in all Contract Documents. Contractor shall perform all Work required by, reasonably inferable from, and consistent with, the Contract Documents. Some of the Contract Documents contain detailed procedures. These detailed procedures and requirements are supplementary to, and do not control, the requirements of the other Contract Documents. Instead, wherever possible, the Contract Documents shall be read together and inconsistencies shall be, were practicable, considered additional requirements to those of the other Contract Documents.

2.1.2 Contract Documents. All Work shall be performed in a professional manner and unless the means or methods of performing a task are specified elsewhere in the Contract Documents, Contractor shall employ methods that are generally accepted and used by the industry, in accordance with industry practices and the Standard of Care. The Contract Documents contain the entire integrated agreement between Contractor and Owner and supersede prior negotiations, representations, and agreements, whether written or oral. The Contract Documents do not create a contractual relationship between Owner and Subcontractors or Sub-subcontractors.

2.1.3 Order of Precedence. In the event of irreconcilable conflicts or discrepancies among the Contract Documents whose requirements cannot be both practicably performed, interpretations shall be based on the following descending order of precedence: (i) Change Orders, with those of later date having precedence over those of an earlier date; (ii) the Agreement; (iii) the Supplemental General Conditions, if any; (iv) the General Conditions; and (v) the Pricing Amendment Documents.

2.1.4 Greater Quality/Quantity. In the case of an inconsistency between Contract Documents as to quantity or quality and not clarified by Addenda, the better quality or greater quantity of Work shall be furnished.

2.1.5 Notice to Owner of Inconsistency. If Contractor finds discrepancies in, or omissions from, the Contract Documents, or if Contractor is in doubt as to their meaning, Contractor shall immediately notify Owner Parties. Responses to Contractor's requests for interpretation of Contract Documents will be made in writing within any time limits agreed upon or otherwise with reasonable promptness and will be consistent with the intent of the Contract Documents. If an inconsistency or interrelation is unresolved, Contractor shall not proceed with affected Work until it receives written direction from Owner Parties.

2.1.6 References to Standards. All references to standards, express or implied, including to standard specifications, manuals, codes of any technical society, organization or association, or laws or regulations of any governmental authority, shall mean the latest standards in effect in the Site's jurisdiction, occurring on the first published date of any solicitation document, except as may be otherwise specifically stated.

2.1.7 Titles and Sections. Some Contract Documents are titled and sectioned for convenience only and such sectioning shall not control Contractor's division of Work among its Subcontractors and the trades and shall not relieve Contractor of responsibility for satisfactory execution of the Work. Owner Parties assume no responsibility for Contractor's division and coordination of the Work.

2.2. Owner's Representative. Owner's Representative will inform Owner of the progress of the Work and will be Owner's advisor during the course of the Work. However, Owner's Representative shall neither be responsible for nor have control of design, construction, means, methods, or procedures, Site or Project safety, and shall have no control over the acts or omissions of Contractor, Subcontractors, Sub-subcontractors, or any other Persons performing Work.

2.3. Contract Administration. Owner Parties shall administer the Contract Documents during construction through Final Completion and during the one-year warranty period for correction of Work. However, Owner reserves the right to perform directly all or some of the roles, and will have all of the rights, designated for Owner Parties in the Contract Documents, including to inspections and rejection of the Work and processing and approving Applications for Payment. In the event Owner chooses to self-perform administration of the Contract Documents, Owner shall not be responsible for or have control of design, construction, means, methods, or procedures, Site or Project safety, and shall have no control over the acts or omissions of Contractor, Subcontractors, Sub-subcontractors, or any other Persons performing Work.

Contractor shall control and shall be solely responsible for safety precautions and programs in connection with the Work.

2.3.1 Communication. Except as otherwise provided in the Contract Documents or when direct communications have been specifically authorized, Owner and Contractor shall endeavor to communicate with each other about matters arising out of or relating to the Contract Documents through Owner Parties. Communications by and with Subcontractors, Sub-subcontractors, and Suppliers shall be through Contractor. Communications by and with Owner's Separate Contractors shall be through Owner's Representative.

2.3.2 Site Visits. Owner Parties will visit the site at intervals appropriate to the stage of the Contractor's operations to become generally familiar with and to keep the Owner informed of the progress and quality of the Work and to guard against defects and deficiencies in the Work. Owner Parties' review of the Work is to determine, generally, if Work is and will be in accordance with the intent of the Contract Documents. Owner Parties will not make exhaustive or continuous on-site inspections to check the quality or quantity of the Work.

2.3.3 Safe Access to Work. Owner Parties shall have access to the Work and the Site at all times. Contactor shall furnish adequate facilities, as required, for Owner Parties to safely access and inspect the Site and the Work, including without limitation, walkways, railings, ladders, tunnels, and platforms. Producers, Suppliers, and fabricators shall also provide proper facilities and access to accommodate Owner Parties' inspections.

2.3.4 Inspections. Work performed and Materials furnished shall be subject to inspection, observation, and testing by Owner Parties at their discretion. Owner Parties' inspection of the Work is to independently determine if the Contract Documents' requirements are met and shall not relieve Contractor of its responsibility to ensure the Work meets the Contract Documents' requirements, including Contractor's own testing and inspection requirements.

2.3.5 Affected Third Parties. When the United States Government pays all or a portion of the Contract Sum, when Owner has an agreement with other public or private organizations, or when a portion of the Work is performed for a third party or in close proximity to third party facilities, representatives of these affected organizations (the "Affected Third Parties") shall have the right to inspect the Work impacting their interests or property. Affected Third Parties' rights to inspect shall not give rise to any status as a party to the Contract Documents, however, and shall not interfere with Owner's or Contractor's rights under the Contract Documents. Communications concerning Affected Third Parties shall be conducted exclusively between the Owner Parties and Contractor.

ARTICLE 3

OWNER'S RIGHTS AND RESPONSIBILITIES

3.1. Owner's Rights.

3.1.1 Right to Reject Work. Owner Parties shall have the authority to reject Work that does not conform to the Contract Documents and to require special inspection or testing of any Work. However, neither Owner Parties' authority to act under this *Section*, nor any decision made by them in good faith, shall give rise to any duty to Contractor, Subcontractor, Sub-subcontractor or any other person performing Work. Work that is Defective Work, in Owner Parties' reasonable judgment, shall be removed from the Site, corrected, and repaired, at Contractor's expense. Work completed or Materials installed that are subject to inspection or testing under the Contract Documents but for which Contractor failed to properly inspect, test, or timely notice Owner Parties, may be ordered removed by Owner Parties at Contractor's expense.

3.1.2 Right to Carry Out the Work. If, within five (5) Days after receiving written demand from Owner Parties to diligently prosecute all or any part of the Work, Contractor fails or neglects to carry out such Work promptly and in accordance with the Contract Documents, Owner may, and without prejudice to any other remedy, make good Contractor's deficiencies.

If Owner carries out Work as set forth above, Owner Parties shall issue an appropriate Change Order deducting from the Contract Sum the cost of correcting such deficiencies, including compensation for Owner Parties' additional services due to such deficiency. If, at the time Owner issues the deductive Change Order, the payments due Contractor are insufficient to cover the deduction in the Contract Sum, Contractor shall immediately pay to Owner the difference.

3.1.3 Right to Clean Up. In the event Contractor and Owner's Separate Contractors dispute responsibility for cleaning up, Owner Parties may direct Contractor to clean up and charge its costs, in Owner Parties' reasonable judgment, to the responsible parties.

3.1.4 Partial Occupancy. Owner shall have the right to occupy and use any completed or partially completed portions of the Work, provided Governmental Authorities having jurisdiction over the Work consent to such occupancy. Substantial Completion shall not be a prerequisite to Owner's

occupancy or use; provided, however, that Owner and Contractor have (a) reasonably accepted in writing their respective responsibilities for payments, retainage, security, insurance, maintenance, heat, utilities, and damage to the Work and (b) agreed in writing to the period for correction of Work and commencement of warranties required by the Contract Documents for those portions of the Work occupied or used. Immediately prior to Owner's partial occupancy or use, Contractor and Owner Parties shall jointly inspect the area to be occupied or used to determine and record the condition of the Work. Partial occupancy or use of a portion or portions of the Work shall not constitute acceptance of Work that fails to conform to the Contract Documents.

3.1.5 Right to Perform Other Work. Owner reserves the right to perform other or additional work at or near the Site with Owner's Separate Contractors. If such work takes place within or adjacent to the Site, Contractor shall coordinate such work and cooperate with Owner's Separate Contractors, to carry out the Work with minimal interference and Delay. Contractor and Owner's Separate Contractors shall place and dispose of materials so as not to interfere with the operations of the other, and shall join the Work with the work of others in an acceptable manner and in proper sequence. In the event of a dispute among Contractor and Owner's Separate Contractors concerning the order or priority of work, Owner Parties' decision shall be final.

3.2. Owner's Responsibilities.

3.2.1 Timely responses and approvals. Owner shall render approvals and decisions with reasonable promptness and shall endeavor to minimize Delay in the orderly progress of Contractor's services and the Work; provided, however, Contractor shall timely advise Owner of the time requirements of such approvals and decisions.

3.2.2 Surveys and Site Data. With prior written request, Owner shall furnish Contractor with all surveys of the Site then in Owner's possession and to the extent necessary to properly perform the Work. Contractor shall review all such materials and promptly notify Owner of inaccuracies or inconsistencies that Contractor discovers. Contractor shall be liable for any inaccuracies or inconsistencies that Contractor discovered or should have discovered in accordance with the Standard of Care, but for which Contractor failed to promptly give to Owner notice.

3.2.3 Other Information or Services. With Contractor's prior written request, Owner shall furnish Contractor with all other information or services then under Owner's control and reasonably required for performance of the Work, with reasonable promptness.

ARTICLE 4

CONTRACTOR'S RIGHTS AND RESPONSIBILITIES

4.1. Contract Documents.

4.1.1 Examination of the Contract Documents. Contractor shall carefully study and examine the Contract Documents and shall at once report to Owner Parties discovered errors, inconsistencies, omissions, and departures from Applicable Laws, including design errors and omissions. By studying the Contract Documents and preparing the Pricing Amendment Documents, Contractor has fully informed itself as to the quality, quantity, and sources of Materials, the character of the Work, and has made a careful examination of the Site and the location and conditions of the Work. As such, Owner shall not be responsible for and Contractor shall have no Claim for losses or unanticipated costs that Contractor suffers due to conditions that Contractor discovered or, as an experienced contractor, should have discovered, but failed to timely report to Owner Parties.

4.1.2 Verification of the Contract Documents. Contractor shall verify all dimensions before laying out the Work, is responsible for the accuracy of all lines, grades, and measurements, and shall protect and preserve all land and survey markers while performing services and executing the Work.

Owner Parties' confirmation of dimensions and layout shall not relieve Contractor of its responsibilities to the same.

4.1.3 Requests for Additional Compensation or Time. If Contractor reasonably believes adjustments to the Contract Documents that would lead to a Change Order are required due to clarifications or instructions issued by Owner Parties in response to the Contractor's notices or requests for information, Contractor shall submit a written request to Owner Parties, setting forth the nature and specific extent of the request, including all time and cost impacts, as soon as possible, but in no event later than twenty-one (21) Days after Contractor's receipt of the clarifications or instructions issued. If Owner Parties deny Contractor's request for additional compensation, and Contractor reasonably believes such denial was in error, the Contractor may file a Claim in accordance with *Article 12* of these General Conditions.

4.2. Use of Site.

4.2.1 Contractor's Operations. Contractor shall confine all Materials, storage, and operations at the Site to the limits indicated by the Contract Documents, Applicable Laws, permits, and direction of Owner Parties.

4.2.2 Adjacent Buildings and Owner's Ongoing Business. Contractor understands the Work performed at the Site will occur around existing buildings, some of which may be historic and frangible, that house and facilitate Owner's current operations. As such, all Work shall be conducted in a manner causing as little interference with and inconvenience to the surrounding structures and continuous conduct of Owner's operations as possible.

4.2.3 Storage and Safekeeping. Contractor shall be solely responsible for storage, handling, and safekeeping at all times of Contractor's and Subcontractors' tools, all equipment including Owner-Supplied Equipment, and all Materials. Contractor shall provide Site and any necessary storage security to guard against vandalism and theft to the Work, tools, all equipment including Owner-Supplied Equipment, and all Materials under Contractor's control and care. Contractor hereby waives all Claims that pertain to the requirements of this *Section*.

4.3. Procedures and Supervision.

4.3.1 General Responsibilities. Contractor shall supervise, coordinate, and direct the Work, using the Contractor's best skill and attention, in accordance with the Standard of Care and shall be responsible for implementing the Construction Plan. Contractor shall be solely responsible for and have control over construction means, methods, techniques, sequences, and procedures, Site and Project safety, and for coordinating all portions of the Work, unless the Contract Documents give other specific instructions concerning these matters. In any event, Contractor shall also evaluate the coordination and jobsite safety of others contributing to the same.

4.3.2 Governmental Authority Coordination. Contractor shall coordinate the Work with all Governmental Authorities and utility companies involved in the Project. Prior to excavation and in accordance with utility locating requirements, Contractor shall cause to have located all underground facilities on and about the Site before commencing any digging operations.

4.3.3 Supervision. Among Contractor's on-Site staff shall be a senior project manager, superintendent, and necessary assistants who shall be satisfactory to Owner Parties and who shall attend the progress of the Work. The project manager shall represent Contractor and all communications given to the project manager shall be binding on Contractor as if given directly to it.

4.3.4 Protection of Work; Mitigation. Contractor shall protect from damage and maintain the Work during the course of construction and shall mitigate any adverse impacts to the Project, including those caused by casualty and by Owner's authorized changes, which may affect Contract Sum, Contract Time, schedules, or quality.

4.3.5 Structure Surveys. Contractor shall cause to be performed comprehensive surveys of the structural components of the Work, verifying its complete conformance with all dimensional and performance requirements of the Contract Documents and Applicable Laws.

4.3.6 Owner's Separate Contractors. Contractor shall provide Owner's Separate Contractors reasonable opportunity to introduce and store at the Site their tools, equipment, and Materials and for the execution of their work. Contractor shall coordinate the Work with the work and services of Owner's Separate Contractors in accordance with the Contract Documents.

Work whose commencement depends upon completion of Owner's Separate Contractors' work shall not be commenced until Contractor inspects such Owner's Separate Contractors' work for conformance with the Contract Documents. In the event Contractor finds Owner's Separate Contractors' work defective or incomplete, Contractor shall promptly report to Owner Parties the apparent issues. Contractor's failure to inspect and report such issues shall, except for latent, concealed defects, constitute an acceptance of Owner's Separate Contractors' work as fit for proper execution of the Work.

Any costs caused by defective or ill-timed Work and any damage to the Work or to Owner's Separate Contractors' work shall be borne by the party responsible for such defect, ill-timeliness, or damage.

4.4. Labor and Materials. Contractor shall provide and pay for all labor, Materials, machinery, utilities, transportation, and other facilities and services necessary for the proper execution and completion of the Work in accordance with the Contract Documents.

4.4.1 Quality of Work. Contractor shall execute the Work with a quality of workmanship consistent with first-class public university projects. Contractor warrants that all Materials shall be new unless otherwise called for in the Contract Documents and that the Work will be free from defects and conform to the Contract Documents' requirements.

4.4.2 Labor and Staffing. Contractor shall maintain sufficient numbers of qualified workers and personnel assigned to the Project to ensure that its obligations under the Contract Documents are timely met. Contractor shall maintain a competent, full-time staff at the Site, including personnel experienced with projects of similar size and scope to that of the Project.

4.4.3 Labor Relations. Contractor is responsible for the actions of all its personnel, laborers, Subcontractors, Sub-subcontractors, Suppliers, and all Persons performing Work on the Project. Contractor shall enforce strict discipline and good order among all Persons carrying out the Work. Contractor shall not permit employment of Persons who are unfit or unskilled for the tasks assigned to them or to whom Owner Parties make reasonable objection.

4.4.4 Medical and Workers' Compensation Payments. As a condition to Owner's performance, Contractor shall promptly, when due, make payment to any person, partnership, association, company, or corporation furnishing medical, surgical, or hospital care or other needed care and attention, incident to sickness or injury, to the Contractor's employees. Contractor agrees to pay for all such services, including from monies the Contractor has collected or deducted from the wages of personnel pursuant to any law, contract, or agreement for providing or paying for such services. Contractor shall comply with and shall ensure all Subcontractors and Sub-subcontractors comply with ORS Chapter 656.

4.5. Quality Management and Control.

4.5.1 Quality Management and Control Plan. Contractor shall develop, seek approval from Owner Parties of, and implement, the Quality Management and Control Plan. The Quality Management and Control Plan is intended to ensure performance of the Work is in accordance with the requirements of the Contract Documents, and implements appropriate procedures to verify and document such compliance. The Quality Management and Control Plan shall include, at a minimum: (i) a breakdown of quality control responsibilities to the various Project participants; (ii) a cost control system for the Work, including regular monitoring of actual costs for activities in progress and estimates for uncompleted tasks and proposed changes; (iii) a quality control matrix listing all testing, inspections, and

Submittals, relating to the Work with specific reference to the source of the requirement and the party responsible (whether Owner Parties, Contractor, or others) for that testing, inspection, and Submittal; (iv) inspection and testing plans for all critical Work, including commissioning and Subcontractors' and inspection agents' activities necessary for the commissioning process; (v) field monitoring and inspection reports; (vi) Contractor's audit plan for auditing Subcontractor's quality control efforts; and (vii) Defective Work identification, reporting, and correction procedures.

Using Contractor's Quality Management and Control Plan, which shall be regularly updated and maintained, Contractor shall inspect the Work on an ongoing basis and document all Defective Work, whether identified by Governmental Authorities, Owner Parties, or Contractor.

4.6. Communication. Contractor and Owner Parties shall develop and implement acceptable procedures for reviewing, documenting, and processing questions and responses, including requests for information, requests for clarification, minor changes in the Work, and Change Orders. If Owner Parties so choose, Contractor shall furnish a web-based system, to facilitate such communications quickly and accurately.

4.6.1 Meetings; Reports. Contractor shall regularly schedule, conduct, and record pre-construction and construction progress meetings. Contractor shall schedule, conduct, and record such progress meetings with Owner Parties at least weekly during construction. For all such meetings, Contractor shall distribute its minutes with promptness after each meeting, to Persons or organizations in attendance.

.1 Contractor shall submit to Owner Parties for review, comment, and approval within fifteen (15) Days after the effective date of the Agreement a form of Contractor's Progress Report. Contractor shall implement and update monthly its approved form of Progress Report.

.2 Contractor shall keep and make available at the Site a regularly maintained log of recordable OSHA incidents and recordable lost time accidents and shall include such log in Contractor's Progress Reports.

.3 Contractor shall keep and make available at the Site a log of Defective Work, as set forth in *Section 4.5.1* above, which shall also be included in Contractor's Progress Reports. Contractor shall maintain communications with Governmental Authorities having jurisdiction and conducting inspections of the Work to ensure timely inspections and adequate time for remedy of Defective Work.

.4 Contractor shall keep and make available at the Site a daily record of Site conditions and activities such as weather, number of workers, Work performed, problems encountered, and other relevant data.

.5 Contractor shall keep and make available at the Site a regularly maintained log of all Submittals.

.6 Contractor shall keep and make available at the Site an accurate record of all tests, inspections, and reports concerning the Work.

4.6.2 Certified Diverse Business Report. Contractor shall submit to Owner Parties its Certified Diverse Report with Contractor's final Application for Payment for each Deliverable Portion of Work.

4.6.3 Schedules. The Project Schedule shall include the overall timeline of all Project activities, major milestones, and phases if any, and shall include the general timeline of the Design and Construction Schedules. Contractor's Design and Construction Schedules shall include (i) all major components and phases of the applicable Work and their associated costs; (ii) break-downs of each major component or phase by building, floor, and trade as applicable; (iii) the time and duration that each

activity will take to completion and accurate estimated float time for each activity; (iv) estimated manpower and cost loading for each phase and, for the Construction Schedule, for each trade within such phase; and (v) the dependencies between all scheduled activities. Contractor shall also include in its Construction Schedule applicable dates of Substantial Completion and Final Completion, and in its Design and Construction Schedules all prerequisite activities to the applicable Work, including processing of Submittals and long lead-time products. Contractor shall adhere to the Project Schedule when managing the Project and to the Design and Construction Schedules when managing and performing the Work. Contractor shall update monthly the Design and Construction Schedules and recommend updates to the Project Schedule as and when necessary. Contractor shall deliver to Owner Parties upon request all native electronic files of all Project, Design, and Construction Schedules so requested.

Owner Parties' acceptance of a Design or Construction Schedule does not constitute agreement as to Contractor's sequencing, means, methods, or durations. Any positive difference between the Contractor's scheduled completion dates, the milestone deadlines, and the Contract Time, is float time owned by the Owner.

4.6.4 Schedule Impacts. Within five (5) Days after occurrence of an event that Contractor reasonably believes will have a material impact on the Work or any schedule, Contractor shall provide written notice to Owner Parties describing the nature and impact of the event, and propose methods of any necessary mitigation.

4.7. Documents and Submittals.

4.7.1 Site Copies. Contractor shall keep and make available at the Site one record copy, in physical or electronic form, of the complete Contract Documents in good order and marked to record field changes and selections made during construction along with one record copy of Owner's Separate Contractors coordinated work. Contractor shall also keep and make available at the Site one copy, in physical or electronic form, of each approved Submittal.

4.7.2 Contractor Review. Contractor shall cooperate with Owner Parties to develop an internet-based system to provide an up-to-date Submittal log. The Submittal log shall include proposed submittal dates and review time for each item, and the approval status of each Submittal.

.1 Contractor shall prepare, review, approve, and submit to Owner Parties, with reasonable promptness and in such sequence as to cause no Delay in the Work or in the work of Owner's Separate Contractors, all Submittals and mock-ups required by the Contract Documents. All Submittals shall be delivered in sufficient time to allow reviewing parties reasonable time for consideration and Contractor adequate time for resubmission if required. Contractor shall cooperate with Owner Parties and coordinate Contractor's Submittals with those of Owner's Separate Contractors.

.2 Prior to Contractor's submission to Owner Parties, Contractor shall cause all Submittals to conform to the Contract Documents, and shall confirm and evidence such conformity with Contractor's review stamp marked "approved." Owner Parties will annotate, correct, and stamp the Submittals as necessary, indicating what further action is necessary and appropriate, and return each Submittal to Contractor. Submittals corrected by Contractor and resubmitted for review and approval containing changes other than those indicated by Owner Parties shall have such additional, new changes, clearly marked to bring them to Owner Parties' attention as well as fully explained in a contemporaneous writing.

.3 In the event a Submittal is not approved, Contractor will be notified of the reasons for disapproval and Contractor shall timely re-submit the revised unapproved Submittal until approved.

.4 By presenting each Submittal to Owner Parties, Contractor represents that it has determined, verified, and approved all Materials and field measurements and criteria

related to that Submittal and has confirmed each such Submittal meets the requirements of the Contract Documents.

.5 If a Submittal requires professional services or certifications, Contractor shall cause each such Submittal document to bear the signature and seal of that professional, as licensed in the state where the Project is located.

.6 Owner Parties' approval of a Submittal shall not relieve Contractor of responsibility for deviation from the requirements of the Contract Documents, unless Owner Parties have given written approval to the specific deviation. The Owner Parties' approval does not imply that the items shown on each Shop Drawing are all-inclusive of Contractor's responsibilities. Subject to the Standard of Care, in no event shall Contractor be relieved of responsibility for errors or omissions, in the Submittals.

.7 No portion of the Work requiring Owner Parties' approval of a Submittal shall be commenced until such Submittal has been approved. Approved Submittals will constitute the standard of quality, appearance, and assembly of all items represented by such Submittals.

4.7.3 Shop Drawings. Shop Drawings shall be submitted, shall be complete, clear, and easily readable, bearing the date of the original submission and of each subsequent resubmission, a title block with Project name and location, and a space for review stamps. All contents of each Shop Drawing shall include the manufacturer, fabricator, and installer, model numbers, schedule designation, and a reference to the Contract Documents requiring the Submittal. Shop Drawings shall be submitted for complete systems. Partial submissions will not be permitted without Owner Parties' prior written approval. Shop Drawings shall also include related work and equipment as appropriate for context and assembly.

4.7.4 Product Data. Product Data, brochures, illustrations, printed charts, schedules, and other such pre-prepared data shall be submitted plus one electronic copy. Such Submittals shall be clearly marked with the particular characteristics or model of the relevant products.

4.7.5 Samples. Upon request, Contractor shall promptly provide a detailed list of all Materials and their respective manufacturers proposed for installation, for Owner Parties' review and approval. The list shall be organized by the Specification section corresponding to each Material, and shall include the installers.

Contractor shall prepare and submit for Owner Parties' review and approval all Samples as required by the Contract Documents. If not otherwise specified, all Samples shall be large enough to clearly show all physical characteristics which have a bearing on selection and appearance and shall be submitted in triplicate. Each Sample transmittal document shall include the Project name and location, manufacturer, fabricator, and installer, model numbers, name, finish, and composition of the items, schedule designation, a reference to the Contract Document requiring the Submittal, and a space for review stamps. Upon approval, the Sample transmittal documents will indicate such approval and two samples will be returned to Contractor.

4.7.6 Purpose and Liability. Submittals are not Contract Documents. Their purpose is to demonstrate the way by which Contractor proposes to conform the Work to the information given and the design concept expressed in the Contract Documents. Owner Parties' review of Submittals is not conducted to determine the accuracy and completeness of other details such as dimensions and quantities, or for substantiating installation instructions, or performance requirements. Owner Parties' approval of a specific item shall not indicate approval of an assembly of which the item is a component.

4.8. Intellectual Property Costs. Contractor shall pay all royalties and license fees arising from the Work, and shall indemnify, defend, and hold harmless Owner from all intellectual property infringement claims arising from or pertaining to the Work, except for those claims concerning a particular design, process, or product selected by Owner Parties or required by the Contract Documents;

provided, however, if Contractor has reason to believe that a design, process, or product infringes an intellectual property right, and fails to timely notify Owner Parties, Contractor shall be responsible for the same.

4.9. Permits; Fees. Unless specifically excluded from Contractor's scope in the Contract Documents, including but not limited to the Fee Matrix set forth in *Exhibit M*, Contractor shall obtain, manage, and pay for all Governmental Approvals that are customarily secured after signing the Agreement, that are legally required at the time the Contract Sum is agreed to, or that are necessary for the proper execution of the Work. Such Governmental Approvals also include, but are not limited to, Contractor's temporary obstructions, enclosures, and Work performed on or about public property other than the Site (e.g., opening of streets for pipes, utilities, environmental work) as required for the Project. Contractor shall give all requisite notices to Governmental Authorities having jurisdiction and shall bear all responsibility for violations of Applicable Laws pertaining to such Work. Nothing in this *Section* shall make Contractor responsible for permits relating to zoning or environmental impact fees.

4.10. Testing.

4.10.1 Contractor's Testing. **[In accordance with Contractor's Quality Management and Control Plan,]** Contractor shall implement its checking and testing procedure at appropriate times during the Project to ensure that all systems, assemblies, and equipment are adequately tested and balanced. In doing so, Contractor shall make or obtain at the appropriate time and shall include in the Contract Sum, all tests, inspections, and approvals of the Work required by the Contract Documents and required by Applicable Laws. Unless otherwise approved or required, testing of the Work shall be conducted by an independent testing service acceptable to Owner Parties.

4.10.2 Notice and Results. Contractor shall give Owner Parties timely notice of when and where tests and inspections are to be conducted so that Owner Parties may be then present. Required certificates of testing, inspection, and approval shall, unless otherwise required by the Contract Documents, be secured by Contractor and promptly delivered to Owner Parties, with any warranties or assurances under such testing, assigned to Owner.

4.10.3 Owner Parties' Testing. If Owner Parties reserve the right to or request to test any Materials or any other portion or component of the Work, Contractor shall furnish samples of such Materials and make available the Work for such testing. Contractor shall cooperate with all such testing performed by others. If Owner Parties determine any Work requires special inspection or testing, Owner Parties may instruct Contractor to order such special inspection or testing. Contractor shall promptly do as ordered, and shall give to Owner Parties reasonable prior notice of the date and time of such special inspection or testing. Any testing performed or requested by or through Owner Parties shall not relieve Contractor of its responsibility to ensure the Work meets the Contract Documents' requirements.

4.10.4 Contractor's Expense. If any inspection or testing reveals Defective Work, or if Work is otherwise not approved by Governmental Authorities having jurisdiction, Contractor shall bear all costs associated with correction of such Work, including compensation for Owner Parties' additional services attributable to such failure.

4.11. Cutting and Patching. Contractor shall be responsible for coordinating all cutting, fitting, and patching of the Work to make its several parts come together properly and fit to receive other Work or the work of others. Contractor shall be responsible for restoring all cut, fitted, or patched surfaces to an original condition; provided, however, that if a different condition is specified in the Contract Documents, then Contractor shall be responsible for causing such surfaces to meet the conditions specified in the Contract Documents. Contractor shall not damage or endanger completed Work, the existing improvements, or the work of Owner's Separate Contractors. Contractor shall not cut or otherwise alter the work of Owner's Separate Contractor except with prior written consent and Contractor shall not unreasonably withhold from Owner's Separate Contractors consent to cutting or otherwise altering the Work.

4.12. Cleaning Up. At all times Contractor shall keep the Site free from accumulation of waste materials, rubbish, and debris. Contractor shall keep and maintain adequate on-Site refuse containers and dumpsters to collect and deposit daily excess construction debris. If Contractor fails to keep the Site in a clean and orderly manner, Owner may, with reasonable prior written notice sufficient to provide Contractor an opportunity to cure, perform cleaning duties and charge their costs to Contractor by offset to any payments due under the Agreement.

In conducting its operations and when performing the Work, Contractor shall use its best efforts to prevent the release of dust and accumulation of mud at the Site. Prior to the dates of Substantial Completion and Final Completion, Contractor shall clean the Site and remove all debris, rubbish, and containers, and take away from the Site Contractor's tools, equipment, machinery, and those surplus Materials to which Owner has chosen not to take possession.

4.13. Project Close-Out.

4.13.1 Close-Out Plan. Contractor shall develop and deliver to Owner Parties a Close-Out plan at least thirty (30) Days before the date of Substantial Completion of the Project or a Deliverable Portion of Work, as applicable. Each Close-Out plan shall establish dates of: (i) Owner's partial and full occupancy of the Project or Deliverable Portion of Work, as applicable; (ii) all relevant Substantial and Final Completion inspections; (iii) expected issuance of all relevant temporary and permanent certificates of occupancy; (iv) equipment startup, balancing, testing, and training; (v) commencement and transfer to Owner of all utility accounts and charges and manufacturer and supplier warranties; (vi) transfer of spare parts and remaining Materials (of which Owner chooses to retain); and (vii) transfer of Record Documents as required.

4.13.2 As-Built Documents. As a condition of Final Completion, Contractor shall provide to Owner a complete set of As-Built Documents, in duplicate and in digital format. As-Built Documents shall depict the Project as constructed and shall reflect each change, modification, and deletion made during construction. As-Built Documents include all modifications to the Contract Documents unless otherwise directed.

4.13.3 Operation and Maintenance Manuals. Contractor shall prepare operation and maintenance manuals ("O & M Manuals") containing a complete set of: all Submittals; training information; a telephone list and contact information for all consultants, manufacturers, installers, and suppliers; manufacturers' printed data; approved relevant Shop Drawings; schematic diagrams of systems; appropriate equipment indices; and warranties and bonds. As a condition to Substantial Completion, Contractor shall submit one (1) electronic version of the completed O & M Manuals for Owner Parties' prior review and approval. Owner Parties may review and provide comments containing any modicitations, adjustments, or additional information required. Owner Parties' receipt of one (1) electronic copy (in PDF file format) of the final approved O & M Manuals shall be a condition precedent to any payment thereafter due.

4.13.4 Training. As part of the Work, and prior to the date of Substantial Completion, Contractor shall schedule with Owner training sessions for all equipment and systems installed as part of the Work. Contractor shall schedule training sessions at least two (2) weeks in advance of the date of training to provide Owner adequate notice and time to coordinate. In addition to any off-site training required, training shall include a formal session conducted at the Project in the users' normal operating environment.

4.13.5 Excess Materials. Contractor shall provide to Owner spare parts, extra maintenance materials, and other Materials, as specified in the Contract Documents, upon Substantial Completion. Any additional Materials not required to be delivered to Owner under the Contract Documents (the "Spare Materials") shall be accounted for by Contractor and offered to Owner. If Owner refuses to accept all or part of the Spare Materials, Contractor shall credit Owner the fair market value of

the unaccepted Spare Materials in the final Application for Payment and shall promptly remove them from the Site.

4.13.6 Contractor's Personnel On-Call. During the first three (3) months following Substantial Completion and Owner's full occupancy of the Project or a Deliverable Portion of Work, as applicable, Contractor shall have appropriate personnel on-call to deal with break-down, inoperability, or other issues with major systems of the Work in accordance with the on-call parameters set forth in *Exhibit __*. If such problems arise at the conclusion of such three (3) month on-call period, all on-call personnel shall remain on-call until the issue proves to be resolved an additional period of not less than two (2) weeks.

4.13.7 Other Responsibilities. Contractor shall be responsible for returning to Owner all of Owner's property issued to Contractor during the term of the Project, including keys, security passes, and site admittance badges. Upon Owner's full occupancy of the Project or a Deliverable Portion of Work, as applicable, and in accordance with the Project's Close-Out plan, Contractor shall coordinate the transfer of all utility company accounts relating to the Project to the Owner.

4.14. Right to Stop Work. If Owner fails to pay to Contractor, within thirty (30) Days after due, any undisputed amount under the Contract Documents, Contractor shall have the right to stop Work after fifteen (15) Days' additional prior written notice to Owner, until Owner delivers to Contractor such overdue payment, with interest, if interest is required by the Contract Documents.

ARTICLE 5

SUBCONTRACTS

5.1. Form and Content.

5.1.1 Form of Subcontract. Upon request, Contractor shall submit to Owner Parties for prior review and approval the form of Subcontract. If Owner Parties disapprove such form, Contractor shall revise and resubmit to Owner Parties the form of Subcontract until approved. Owner Parties' review, comment upon, and approval of, any such form, shall not relieve Contractor of its obligations under this Agreement. Unless otherwise waived in writing by Owner, all Subcontracts shall be awarded on a fixed lump-sum price basis. Upon request, Contractor shall supply Owner Parties with copies of all fully-signed Subcontracts.

5.2. Certain Terms of Subcontract. In addition to Owner Parties' right to review Subcontracts in Section 5.1.1 above, certain terms shall be included in each Subcontract, as set forth below:

.1 Owner shall be a third party beneficiary of each Subcontract and Owner's rights and remedies under each Subcontract shall be all those of Contractor, including the right to be compensated for any loss, expense, or damage incurred resulting from Subcontractor's breach of express or implied terms and Subcontractor's error, omission, or negligence in its performance;

.2 following advance written notice to Contractor, Owner Parties may contact Subcontractor, to discuss Subcontractor's services; provided, however, such contact with Subcontractor shall not be construed to be Owner Parties' instructions concerning performance of Work;

.3 each Subcontractor shall meet the insurance requirements set forth in these General Conditions, including, but not limited to, naming Owner as an additional insured on applicable liability policies;

.4 a "no damage for delay" clause as set forth in *Section 7.2.6* of these General Conditions;

.5 a payment clause that obligates Subcontractor to pay its Sub-subcontractors for Work satisfactory performed but unpaid within ten (10) Days of Contractor's payment to Subcontractor for such Work;

.6 Contractor's rights and duties under the Subcontract shall be assignable, for the same fixed lump-sum price, to Owner or Owner's designee upon Owner's written notice to Subcontractor and to Contractor;

.7 Subcontractor shall expressly consent to conditional assignment to Owner of its Subcontract and continued diligent performance of Work;

.8 Subcontractor shall promptly notify Owner of any Contractor default, whether under the Agreement, or its Subcontract;

.9 Contractor may terminate upon ten (10) Days' prior written notice each Subcontract for a default or convenience identical in substance to Owner's right to terminate under *Section 13.2* of these General Conditions.

5.2.2 Flow-Down. Contractor shall require each Subcontractor and each Subcontractor shall require each Sub-subcontractor, to be bound by these General Conditions and any Supplemental General Conditions, and to assume toward Contractor and Subcontractor, as the case may be, all of the obligations and responsibilities the Contractor assumes toward the Owner, unless (i) the same are clearly inapplicable to the contract at issue because of legal requirements or industry practices, or (ii) Contractor requests specific exceptions that Owner approves in writing.

5.3. Conditional Assignment. Contractor hereby conditionally assigns to Owner its rights to all Subcontracts, subject to Contractor's sureties' rights, under their bonds. Owner may exercise, at its election, this assignment if Owner terminates the Agreement in whole or in part, or directly or indirectly takes control of all or any portion of the Work. In so doing, Owner may reassign the Subcontracts to any other Person or entity.

5.4. Right to Review. Owner has the right to review Subcontracts at any time during the Project and at any time during an audit period, if prescribed in the Contract Documents, after Final Completion. Contractor shall, within three (3) Days of receiving written request from Owner or Owner's agent, submit to the requesting party a complete copy of the requested Subcontract. If Owner's or Owner's agent's request to review a Subcontract can be interpreted to cover more than one Subcontract, Contractor shall submit complete copies of all Subcontracts relevant to the request.

5.5. Conditions to Payment. As a condition to Owner's performance, Contractor shall: (i) make payment promptly when due, and in no event greater than ten (10) Days after receiving payment from Owner, to all Persons supplying to Contractor services, labor, or Materials for prosecution of the Work; (ii) pay all contributions required by and amounts due the State Industrial Accident Fund incurred in performance of the Contract Documents; (iii) not permit any lien or bond claim to be filed or prosecuted against Owner or surety on account of any labor or Material furnished; (iv) not assign any claims or Claims that Contractor may have against Owner, nor assign any rights to payment from Owner, and will not make any agreement or act in any way to give Subcontractors standing to bring a claim or a Claim against Owner; (v) pay to the Department of Revenue all sums withheld from employees pursuant to ORS 316.167.

ARTICLE 6

PAYMENT

6.1. **Contract Sum**. A Contract Sum shall be subject to adjustment only when Owner so authorizes in writing.

6.2. **Sales and Use Tax**. As a condition precedent to commencement of the Work, Owner and Contractor shall agree upon a sales and use tax (collectively, "Taxes") applicability guideline. In the event Tax is chargeable to any portion of the Work, the Contract Sum shall include all such Tax unless directly paid by Owner. In the event Contractor pays such Tax directly, all invoices and Applications for Payment that include Work subject to Tax shall clearly state "sales tax paid" and specifically identify such taxable Work. In the event Owner pays such Tax directly, the Contract Sum shall not include Tax and Owner shall provide to Contractor the necessary certificates evidencing the same.

6.3. **Schedule of Values**. Contractor shall submit to Owner Parties for approval, at least ten (10) Days prior to submission of its first Application for Payment, a Schedule of Values. Contractor shall revise and resubmit the Schedule of Values as necessary to meet Owner Parties' approval. The Schedule of Values shall demonstrate reasonable, identifiable, and measurable components of the Work, as separate line items for each major item of Work, and Construction Contingency, among other items as Owner Parties may reasonably require, all of which shall be supported by data to substantiate its accuracy. The approved Schedule of Values, unless objected to by Owner Parties, shall be used as a basis for reviewing Contractor's Applications for Payment. Once approved, Contractor's requested changes to the Schedule of Values shall be subject to Owner Parties' prior approval and supported by data to substantiate its accuracy.

6.4. **Periodic Statements**. Upon request from time to time, Contractor shall provide to Owner Parties a written summary of all outstanding, incomplete Work necessary to achieve Final Completion, and the total unpaid cost of that Work (a "Statement of Outstanding Work"). Each Statement of Outstanding Work shall contain sufficient information to allow Owner Parties to determine if the applicable Work can be completed for the Contract Sum and within the Contract Time. However, no such statement shall relieve Contractor of its obligations to complete the applicable Work for the Contract Sum and within the Contract Time.

6.5. **Applications for Payment**.

6.5.1 Supporting Documents. For each payment period established in the Agreement, Contractor shall submit to Owner Parties, an Application for Payment, together with: (i) an updated Progress Report; (ii) a schedule of the percentages of the various parts of the Work completed, based on the Schedule of Values; (iii) Contractor's and Subcontractors' payroll certifications pursuant to *Section 1.5.4* of these General Conditions; (iv) up to date Project Schedule, Design Schedule, and Construction Schedule; and (v) other supporting documentation as required by the Specifications and the Agreement (collectively, the "Supporting Documents").

6.5.2 Accuracy of Application. Applications for Payment shall be accurate and based upon estimates of Work completed in accordance with the Schedule of Values. Each Application for Payment shall include, on the face of each copy, Contractor's statement in substantially the following form, dated and bearing Contractor's signature:

> "I, the undersigned, hereby certify that the above Application for Payment is true and correct, and payment for the same, has not yet been received."

Owner Parties may reject any improper or incomplete Application for Payment until Contractor corrects and resubmits the same. However, Owner Parties reserve the right, instead of requiring Contractor to correct or resubmit a defective or improper Application for Payment, to reject the defective or improper

portion of such Application for Payment and pay the remainder of such amounts that are proper and correct.

6.5.3 Stored Materials. Unless otherwise provided in the Contract Documents, Owner shall make payments on account of Materials not incorporated in the Work but delivered and suitably stored at the Site. If approved by Owner in advance, Owner may similarly make payments for Materials suitably stored at a location other than the Site, if agreed upon in writing. As a condition precedent to Owner's payments for Materials stored on or off the Site, Contractor shall submit with its Applications for Payment that include such Materials, photographs of Materials and evidence (e.g., bills of sale), satisfactory to Owner to establish Owner's title to or otherwise protect Owner's interest in, the same.

.1 Contractor shall include with its Applications for Payment that include Materials stored off-Site, costs and evidence of applicable insurance, storage, and transportation to the Site. Owner Parties shall have the right to access, remove, and inspect, at any time during the Project, Materials stored off-Site for which Owner has paid.

.2 In consideration of Contractor's ability to store certain Materials off-Site, Contractor waives and releases any Claims it may have against Owner, either directly or through Contractor's insurer, for damage to or loss of, such Materials not stored at the Site.

.3 Contractor shall name Owner as additional named insured on the insurance policy covering the full value of the property while in the care and custody of the Contractor until installed in the Project. A certificate noting this coverage shall be issued to Owner.

6.5.4 Failure to Pay Subcontractors and Suppliers. Applications for Payment shall not include requests for payment of Work for which Contractor does not intend to pay a Subcontractor or Supplier assigned to such Work, unless Contractor intends to pay others who actually performed such Work.

6.5.5 Title to Instruments of Service and Work. Contractor warrants that title to all Instruments of Service and Work covered by each Application for Payment will pass to Owner no later than the time of payment on account of such Application for Payment. Contractor further warrants that upon submittal of each Application for Payment, all Work for which payments have been received shall be free and clear of all liens, bond claims, Claims, security interests, and other encumbrances arising from or relating to the Work. This *Section* shall not relieve Contractor of: (i) its sole responsibility for all Work, (ii) any obligation to restore damaged Work, or (iii) its requirement to fulfill of all the terms of the Contract Documents, including, but not limiting, correction of any Defective Work. However, until Owner takes occupancy of all or any portion of the Project, as the case may be, all Work and Materials shall continue to be in the care and custody of Contractor, who shall bear the risk of loss for the same except to the extent insured pursuant to *Article 8*. The provisions of this *Section* concerning title to Work for which Owner makes payment shall not constitute an acceptance of the Work, except as otherwise set forth in the Contract Documents.

6.5.6 Incorrect Applications for Payment. If an Application for Payment is incorrect, lacks the required Supporting Documents set forth in *Section 6.5* of these General Conditions, or when there is a good faith dispute concerning the Work for which it is submitted, Owner Parties shall endeavor to notify Contractor within fifteen (15) Days of its receipt of such Application for Payment, stating the reasons it is rejected. If Contractor corrects the rejected Application for Payment within seven (7) Days of Owner Parties' notification to Contractor, payments due shall be made in accordance with *Section 6.7* below.

6.6. Certificate for Payment. Owner Parties will review each Application for Payment and either: (i) issue to Owner a Certificate for Payment indicating Contractor is due the amount set forth in such Application for Payment; (ii) issue to Owner a Certificate for Payment indicating Contractor is due an amount less than as requested, in which case the Certificate shall state the amount due, or (iii) notify

Owner in writing of reasons to withhold payment. In the event Owner Parties determine Contractor is not entitled to the amount requested in an Application for Payment, Owner Parties shall forward to Contractor the reasons for withholding all or a portion of the payment requested. In the event Contractor disputes amounts withheld, Contractor shall have a Claim for such amounts.

Owner Parties' issuance of a Certificate for Payment constitutes a representation to Owner that, based on Owner Parties' Site observations and the data comprising the Application for Payment, the Work has progressed to the point indicated in Contractor's Application for Payment, that, to the best of Owner Parties' knowledge, information, and belief, the quality of the Work is in accordance with the Contract Documents, and that Contractor is entitled to payment in the certified amount.

6.7. Progress Payments. Provided no liens or bond claims related to the Work have been filed against the Project after Owner Parties issue a Certificate for Payment, and provided no Governmental Authorities have raised objections to the Work, Owner shall make payment to Contractor in the manner set forth in the Agreement. Upon its receipt of Owner's payment, Contractor shall promptly and within ten (10) Days, pay each Subcontractor the amount to which it is entitled, on account of such Subcontractor's Work, and each Subcontractor shall promptly pay its Sub-subcontractors and Suppliers in similar fashion. Owner Parties shall not, however, have any obligation to see that monies due to any Subcontractor are so paid, except as may otherwise be required by law.

6.7.1 Payment Not Acceptance. Owner's progress payments, partial payments, final payment, and Owner's use or occupancy of all or a part the Project, shall not constitute an acceptance of any Defective Work.

6.7.2 EFT Payments. Owner, upon written notice to the Contractor, may elect to make payments to Contractor by means of Electronic Funds Transfers (EFT) through automated clearinghouse payments. If Owner makes this election, Contractor shall make the necessary arrangements to receive such EFT payments.

6.7.3 Payment Directly to Subcontractors. Unless Contractor advises Owner of a good faith dispute concerning payment due to a Subcontractor or Supplier, Owner may make payments directly or jointly to Subcontractors and to Suppliers who seek payment for work included in an Application for Payment. Contractor shall credit against the Contract Sum such amounts that Owner directly pays. However, Owner's direct payments to Subcontractors or Suppliers shall not relieve Contractor or Contractor's surety from their obligations to payment claims or demands.

6.7.4 Retainage. Owner will not retain an amount in excess of five percent (5%) of that portion paid for Work completed. If Contractor has performed at least fifty percent (50%) of the Work of a Deliverable Portion of Work and is progressing satisfactorily, upon the Contractor's submission of written application containing the surety's written approval, Owner Parties may, in their sole discretion, reduce or eliminate retainage on any remaining progress payments for that Work. Owner Parties will respond in writing to all such applications within a reasonable time. Upon Contractor's written recommendation to Owner Parties, which shall necessarily include applicable sureties' written approval, Owner will consider early release of retainage for Subcontractors whose Work is completed prior to Substantial Completion of all applicable Work; provided, however, the final decision whether to release such retainage shall be in Owner's sole discretion and Contractor shall promptly pay the same to the appropriate Subcontractor. When the Work of a Deliverable Portion of Work is ninety-seven and one-half percent (97.5%) completed, Owner Parties may, in their sole discretion and without application by the Contractor, reduce the retainage amount to one hundred percent (100%) of the remaining unpaid Contract Sum. Owner Parties may at any time reinstate retainage. Retainage will be included in the final payment under the Contract Documents.

If the Contract Sum exceeds one million dollars ($1,000,000), Contractor may request retainage be deposited in an interest-bearing account at a financial institution upon which Owner and Contractor agree. Title to such retainage funds will remain in the Owner until the applicable Work is complete and

accepted. Interest on deposited retainage, less the financial institution's fees necessary to open and maintain the account, shall accrue to the benefit of the Contractor but remain in the retainage account until the Owner accepts all Work.

6.7.5 Subcontractor Retainage. Unless Owner gives prior approval, Contractor's payments to Subcontractors and Suppliers shall be subject to retainage of five percent (5%).

6.7.6 Retainage Alternatives. In lieu of cash retainage as set forth above, Contractor may substitute one of the following:

.1 *Deposit of Securities*. Contractor may deposit bonds or securities with Owner or in any bank or trust company approved by Owner, as retainage. In any event, all such bonds and securities shall be held for Owner's benefit. Bonds and securities deposited or acquired in lieu of cash as retainage will be of a character approved by Owner, including: (i) bills, certificates, notes, or bonds of the United States; (ii) other obligations of the United States or its agencies; (iii) obligations of any corporation wholly owned by the United States federal government; or (iv) indebtedness of the Federal National Mortgage Association.

If Contractor deposits bonds or securities in lieu of cash as retainage, the cash value of such bonds or securities will reduce the cash retainage by an equal amount, and Owner shall reimburse Contractor the excess cash retainage. Following Final Completion, after Owner determines all requirements for the protection of its interests have been fulfilled, Owner will release to the Contractor all bonds and securities deposited in lieu of cash as retainage.

.2 *Deposit of Surety Bond*. Owner may, in a form acceptable to it and in its sole discretion, allow Contractor to deposit with Owner a surety bond as retainage in lieu of all or a portion of cash retainage or to be retainage for the Project. A Contractor depositing such a surety bond shall also accept surety bonds from Subcontractors and Suppliers in lieu of cash as retainage. If Contractor deposits a surety bond as retainage, the value of such bond will reduce the cash retainage by an equal amount, and Owner shall reimburse Contractor the excess cash retainage.

6.7.7 Retainage Handling Costs. Owner shall have the right to recover from Contractor by reduction to the final payment, its costs for handling cash retainage and securities.

6.7.8 Release of Retainage. Owner's release of retainage shall not constitute acceptance of Work that fails to conform to the Contract Documents.

6.8. Right to Withhold Payment. Notwithstanding any provision of the Contract Documents to the contrary, Owner shall have the right to withhold payment to Contractor as necessary to protect itself if, after written notice and reasonable opportunity to cure: (i) Contractor is in default of any of its Contract Documents obligations; (ii) Owner reasonably believes any part of a payment due is attributable to Work that fails to conform to the Contract Documents' requirements, except that Owner shall make payment attributable to Work that does conform to the Contract Documents' requirements; (iii) Contractor causes damage to the Work, Owner, or Owner's Separate Contractors; (iv) Contractor fails to timely make payments due and owing to Subcontractors or Suppliers who contributed to Work for which Owner has paid Contractor and for which Contractor has given to Owner no notice of its good faith dispute concerning the unpaid Subcontractor or Supplier; (v) reasonable doubt that Contractor can complete the Work in accordance with the Contract Documents, including the Construction Schedule; (vi) Owner determines, based on a Statement of Outstanding Work or otherwise, that the Work of a Deliverable Portion of Work cannot be completed for the Contract Sum unless and until Contractor furnishes a reasonable and satisfactory statement and plan showing and certifying that the Work can be completed for the Contract Sum, or Contractor, at no cost to Owner, causes a sufficient portion of the applicable Work to be performed such that the unpaid portion of the Contract Sum is reasonably sufficient to complete the Work; (vii) reasonable evidence that the Work of a Deliverable Portion of Work will not be completed within the Contract Time, and the unpaid Contract Sum balance will not be adequate to

cover Owner's damages for the Delay; (viii) entitlement to offset for assessment of Liquidated Damages; (ix) reasonable evidence of probable third party claims, unless Contractor furnishes to Owner acceptable security.

6.9. Completion Milestones.

6.9.1 Substantial Completion. When Contractor considers a Deliverable Portion of Work Substantially Complete, Contractor shall prepare for Owner Parties' review and approval a comprehensive list of incomplete and unsatisfactory items. Owner Parties will edit and supplement this list, as appropriate, and when approved the list shall be the Punch List for such Deliverable Portion of Work. Contractor and Owner Parties shall also, at the same time they develop the first Punch List, establish a schedule (the "Punch List Schedule") setting forth anticipated dates for Owner Parties' inspections of all anticipated Deliverable Portions of Work to determine Substantial Completion and Final Completion of the same.

.1 Notwithstanding anything to the contrary contained in the Contract Documents, a Deliverable Portion of Work with systems - e.g., mechanical, electrical, HVAC - shall not be considered Substantially Complete until it has demonstrated a minimum of thirty (30) consecutive Days of successful, trouble-free operation, beginning after all inspections and testing have been completed for such Deliverable Portion of Work.

.2 Once a Punch List and Punch List Schedule are mutually accepted, Owner Parties will inspect the Project to determine if each Deliverable Portion of Work is Substantially Complete. During inspection, if Owner Parties determine any incomplete or incorrect item, whether or not included on the Punch List, causes the Deliverable Portion of Work to fail to be Substantially Complete, Contractor shall be given notice and shall promptly correct such item. Following completion of all incomplete items, Contractor shall request that Owner Parties' re-inspect the Deliverable Portion of Work to again determine if it is Substantially Complete. When Owner Parties determine a Deliverable Portion of Work is Substantially Complete, Owner will prepare a letter (a "Substantial Completion Letter") that will establish the date of Substantial Completion of that Deliverable Portion of Work, fix the time within which Contractor shall complete and correct items noted in that Substantial Completion Letter, and designate the responsibilities of the Owner and Contractor for security, maintenance, utilities, and insurance pertaining to such Deliverable Portion of Work.

.3 Upon receipt of a Substantial Completion Letter, Contractor shall diligently complete all items of incomplete Work and repair all Defective Work, including those identified in the applicable Punch List and Substantial Completion Letter. However, failure by any party to include an item on the Punch List or in the Substantial Completion Letter shall not alter Contractor's responsibility to complete all Work in accordance with the Contract Documents.

.4 In accordance with the Punch List Schedule, Owner Parties anticipate they will make an initial visit and one re-inspection for each of Contractor's Deliverable Portions of Work. If, after making a re-inspection, Owner Parties determine a Deliverable Portion of Work is not Substantially Complete or that previously scheduled Punch List Work has not been completed, Contractor shall pay, without Owner's reimbursement, Owner Parties' costs and expenses resulting from additional inspections necessary for Owner Parties to issue Certificates of Substantial Completion.

6.9.2 Payment Upon Substantial Completion. When Owner Parties issue a Substantial Completion Letter and Contractor submits an applicable Application for Payment, Owner shall make payment to Contractor, reflecting adjustment in retainage, if any, as provided in the Contract Documents. However, Owner shall not release retainage to Contractor that will result in Owner holding total retainage

less than twice the amount that Owner Parties determine necessary to complete and correct all items on an applicable Punch List.

6.9.3 Commencement of Warranties. Applicable warranties required by the Contract Documents shall commence on the date of Substantial Completion of each Deliverable Portion of Work unless otherwise set forth in a Substantial Completion Letter. Contractor will collect all written guaranties, warranties, and equipment manuals, and deliver them to Owner upon Substantial Completion of each Deliverable Portion of Work.

6.9.4 Delay. After Owner Parties issue a Substantial Completion Letter for a Deliverable Portion of Work, if Final Completion of that Deliverable Portion of Work is subject to material Delay through no fault of Contractor or by the issuance of Change Orders affecting Final Completion of that Deliverable Portion of Work, Contractor shall be entitled to the balance due for that Deliverable Portion of Work fully completed, accepted, and certified as complete by Owner Parties. However, if the balance of the Contract Sum for Work not fully completed or corrected is less than the retainage then held by the Owner and bonds have been furnished for the Project, Contractor shall forward to Owner Parties the written consent of Contractor's surety to the payment of the balance due for Work fully completed and accepted. Any such payment shall not constitute a waiver of Owner's Claims.

6.9.5 Final Completion. Following (a) issuance of a Substantial Completion Letter for a Deliverable Portion of Work and (b) Contractor's completion of all Work of that Deliverable Portion of Work, including the applicable Punch List, but not more than forty-five (45) Days after Substantial Completion, Contractor shall forward to Owner Parties written notice that the applicable Work is ready for inspection together with a final Application for Payment for such Work. Upon receipt, Owner Parties will promptly inspect the subject Work and, when Owner Parties determine the Deliverable Portion of Work meets the Contract Documents' requirements, will issue a Certificate for Payment approving final payment due Contractor for the applicable Work.

.1 Owner Parties' approval of a final payment represents that, to the best of Owner Parties' knowledge, information, and belief, and on the basis of observations and inspections, the Work subject to final review and payment has been completed in accordance with the terms and conditions of the Contract Documents, the conditions precedent to Contractor's entitlement to final payment for the Deliverable Portion of work are met, and the entire balance noted in the applicable Certificate for Payment is due and payable to Contractor.

.2 As part of Contractor's notice to Owner Parties of Final Completion, or as a separate written notice submitted with or before the notice of Final Completion, and as a condition precedent to Owner's obligation to make final payment, Contractor shall furnish Owner Parties with written confirmation that all environmental and pollution clean-up, remediation, and closure have been completed in accordance with all Applicable Laws. Contractor shall provide to Owner Parties all documentation related to the same, including directives, orders, letters, certificates, and permits. Contractor's notice shall further reaffirm its grant to Owner of indemnification given under *Section 9.5.3* of these General Conditions.

6.9.6 Payment Upon Final Completion. The final payment requirements of this *Section 6.9.6* shall apply to the Project and to Deliverable Portions of Work, as applicable and as set forth in the Contract Documents. Final payment, including release of all retainage, shall not be due until Final Completion of the Project of the Deliverable Portion of Work, as applicable, and until Contractor has timely furnished to Owner Parties: (i) an affidavit stating that to Contractor's best knowledge, information, and belief, all payrolls, bills for Materials, and other indebtedness connected with such Work (less amounts withheld by Owner) have been satisfied; (ii) payroll certifications pursuant to *Section 1.5.4* of these General Conditions (iii) a certificate evidencing that insurance required by the Contract Documents to remain in force after final payment is and will remain in effect and will not be canceled or expire without at least thirty (30) Days' prior written notice to Owner; (iv) Contractor's written statement

that it knows of no reason all required insurance will not be renewable to cover the period required by the Contract Documents; (v) all warranties and guaranties required by the Contract Documents; (vi) three reproducible copies and an electronic copy of Record Documents; (vii) surety's consent to final payment; (viii) applicable Certified Diverse Business Reports; (ix) final affidavits and releases of liens and bond claims, as well as satisfactions for liens and bond claims filed on account of the Work of the Deliverable Portion of Work and such other affidavits, waivers, and releases as Owner may reasonably require in order to assure lien and claim-free completion of such Work; and (x) if Owner requires, other data establishing payment or satisfaction of obligations, such as receipts, releases and waivers of liens, claims, Claims, security interests or encumbrances arising out of the Deliverable Portion of Work, to the extent and in such form as may be reasonably designated by Owner. If any such lien or bond claim remains unsatisfied after final payment, Contractor shall immediately refund to Owner all monies that the latter may be compelled to pay in discharging such lien or bond claim, including all costs and reasonable attorney fees.

.1 Contractor's acceptance of final payment shall constitute a waiver of all Claims applicable to the Deliverable Portion of Work for which such final payment is made by Contractor, Subcontractors, Sub-Subcontractors, Suppliers and all other Persons delivering services, labor, or Materials to the Project, except those previously made in writing and identified by Contractor as unsettled, at the time of the applicable final Application for Payment.

.2 Owner's final payment shall not extinguish, satisfy, or waive any of the Contract Documents' obligations or procedures.

6.9.7 Final Inspection. On or about a date eleven (11) months after Substantial Completion of a Deliverable Portion of Work, Contractor shall, together with Owner Parties, attend a final inspection of the Work to ensure that it comports with all warranties and guarantees. Contractor shall promptly correct any deficiencies noted during such inspection.

6.10. No Liens; No Bond Claims. Contractor shall permit neither the Project nor any of the Work from incurring any claim, bond claim, lien, charge, or encumbrance. Contractor shall, after first receiving notice of any such claim, bond claim, lien, charge, or encumbrance, immediately pay and discharge of record the same.

ARTICLE 7

TIME

7.1. Progress and Completion. All time limits stated in the Contract Documents are of the essence of the agreement between Owner and Contractor. Contractor shall begin each phase of the Project, where applicable, in accordance with the Project Schedule and shall commence the Work on the dates set forth in the applicable Design and Construction Schedules. Contractor shall carry out the Work expeditiously, with adequate forces, and shall achieve Substantial Completion in accordance with the Project's milestones, the Construction Schedule, and within the Contract Time.

7.1.1 Periodic Statements. At Owner's request, from time to time, Contractor and Owner Parties shall each provide a written statement setting forth the date on which each reasonably believes each Deliverable Portion of Work will be Substantially Complete. However, no such statement shall relieve Contractor of its obligations to complete the Work in accordance with the Contract Documents.

7.1.2 Acceleration Upon Default. If, in Owner Parties' reasonable judgment, Contractor: (i) fails to supply a sufficient number of qualified workers or Materials to prevent Delay; (ii) fails in any way to prosecute the Work or proceed in accordance with the Design or Construction Schedules, or (iii) fails to meet the material covenants of the Contract Documents, Owner shall have the right to direct Contractor to accelerate completion of the Work without adjustment to the Contract Sum

and until such time as the amount and timing of the completed Work complies with the applicable schedules. Owner's right to compel acceleration includes demanding Contractor provide additional labor or expedited deliveries of Materials, and perform overtime, additional shifts, or re-sequencing the Work. Costs of such acceleration may be funded, with Owner's prior written approval, from any available Construction Contingency, if not recoverable from Subcontractors. Owner's right to demand acceleration under this *Section* shall not limit other rights and remedies Owner may have.

7.2. Delays and Extension of Time.

7.2.1 Delays Generally. Contractor shall be granted an extension of time for each Unavoidable Delay (defined below) in accordance with *Section 7.2.4* below. Contractor shall not be granted an extension of time for any Avoidable Delay (also defined below).

7.2.2 Force Majeure. "Force Majeure" shall mean an act, event, or occurrence caused by fire, riot, war, acts of God, tornado, hurricane, named storms, flood, earthquake, explosion, public enemy, civil disturbance, embargo, unusual and abnormal severe and adverse weather, or any other act, event or occurrence that is beyond the reasonable expectation or control of the party who is asserting an inability to conform to Contract Documents' requirements. Unusually and abnormal severe and adverse weather shall not include weather events that could be reasonably anticipated from the previous 10-year historical records of the general locality of the Site. Such historical records shall be from the Office of the Environmental Data Service of the National Oceanic and Atmospheric Administration of the U.S. Department of Commerce nearest the Site. However, notwithstanding such historical records, (a) daily rainfall greater than one-half (1/2) inch during a month when the monthly rainfall exceeds the normal monthly average by at least twenty-five percent (25%) or (b) daily rainfall greater than three (3) inches, cannot be reasonably anticipated.

7.2.3 Avoidable Delays. An "Avoidable Delay" is any Delay other than an Unavoidable Delay, and those Unavoidable Delays that could have been avoided, because: (i) Contractor, Sub-contractors, or Sub-subcontractors failed to exercise care, prudence, foresight, or diligence; (ii) such Delay only affects a portion of Work that does not necessarily interfere with prosecution of other parts of the Work; (iii) such Delay does not impact the Project's critical path; or (iv) such Delay results from Owner's Separate Contractors' work that does not necessarily prevent the timely completion of all Work.

7.2.4 Unavoidable Delays. An "Unavoidable Delay" is any Delay that is not due to the direct or indirect fault of Contractor, Subcontractor, Sub-subcontractors, Suppliers, or any of their respective agents, employees, or contractors, and that affects the Project's critical path. Unavoidable Delays include: (i) Delays caused by Owner and Owner's employees and agents, or by Owner's Separate Contractors; (ii) Delays caused by Force Majeure that in fact adversely impact the Project in a manner that could not have been avoided by rescheduling or by implementing protective measures; (iii) Delays caused by any differing Site conditions in accordance with *Section 10.3.4* of these General Conditions.

If Contractor's delivery of services or performance of the Work is impacted by an Unavoidable Delay, Contractor's sole remedy shall be an equitable extension to time and a Claim for documented increases to on-Site general conditions costs; provided, however, in each instance Contractor must first meet the notice provisions and other conditions of the Contract Documents, including *Section 12.1* of these General Conditions. Notwithstanding the foregoing, Contractor shall not be granted relief: (i) due to Contractor's financial inability to perform; (ii) unless a Delay is an Unavoidable Delay and affects the Project's or phase's critical path as set forth in the applicable Construction Schedule, and then only to the extent such critical path is affected; or (iii) if a Delay would have resulted because of Contractor's concurrent Avoidable Delay, notwithstanding the existence of an Unavoidable Delay.

7.2.5 Mitigation Required. Contractor shall use best efforts to remove, relieve, minimize, and mitigate the effect of all Delays, no matter the cause.

7.2.6 No Damage for Delay. To the fullest extent permitted by Applicable Laws, unless otherwise set forth in the Contract Documents, Contractor shall have no Claim against Owner

Parties for any increase in the Contract Sum, damages, losses, or expenses, resulting from a Delay, unless Owner or its agents actively interfered and directly caused such Delay, in which case Contractor's Claim shall be limited to reimbursement for Contractor's actual and direct costs, expressly excluding impact costs such as extended home office, overhead, and loss of profit.

7.3. Owner-Caused Schedule Changes. Contractor acknowledges and agrees as the Project progresses, as is customary among projects of this size and complexity, Owner may make changes to, and Contractor shall subsequently update, the Project Schedule. Contractor shall cooperate with and advise Owner Parties of potential outcomes of such changes including their impact on the Design and Construction Schedules. If Owner subsequently approves any such change, Contractor will have a Claim, but only if the approved change impacts the critical path of the applicable Construction Schedule.

7.4. Phased Construction.

7.4.1 Phases. Contractor acknowledges and agrees the Project will progress in phases, in accordance with the Project Schedule. Contractor shall prepare, for Owner Parties' review and approval, a separate Construction Schedule, for each phase. Each phase shall commence upon Owner Parties' issuance of a Notice to Proceed for such phase and shall achieve Substantial Completion by the milestone dates set forth in the Contract Documents, including the Construction Schedule.

7.4.2 Contract Sums. Owner may choose to establish separate Contract Sums for each phase of the Project and, if so, Contractor shall cooperate to prepare and timely deliver to Owner when due such Contract Sums as set forth in the Project Schedule.

7.4.3 Fast-Track Methods. Contractor represents to Owner that it has experience and expertise in fast-track construction and management practices. As such, Contractor acknowledges, agrees, and will actively participate in project planning, that may necessitate preparation, issuance, and analysis of a number of bid packages in excess of that which is ordinarily required in non-fast-track construction projects.

7.4.4 Waiver of Claims. In consideration of the foregoing, Contractor hereby waives all rights and remedies it may have at law or in equity to extra compensation or damages of any kind, and to extensions to the Project, Design, and Construction Schedules, due in any way to performance or planning of the Work on a fast-track basis.

ARTICLE 8

INDEMNITY; INSURANCE; BONDS

8.1. Contractor Responsibility. Contractor shall be responsible for all damage to property, injury to persons, and loss, expense, inconvenience, and delay caused by, or resulting from, performing its services and carrying out the Work. "Indemnitees" as used in this *Article 8* shall mean Owner Parties, and their respective officers, board members, shareholders, members, partners, directors, affiliates, agents, assigns, attorneys, and employees.

8.2. Indemnification.

8.2.1 General Indemnity. **TO THE FULLEST EXTENT PERMITTED BY LAW, CONTRACTOR SHALL INDEMNIFY, DEFEND, AND HOLD HARMLESS, THE INDEMNITEES, FROM ALL LIABILITIES, DAMAGES, LOSSES, EXPENSES, AND COSTS, INCLUDING REASONABLE ATTORNEY FEES AT BOTH THE TRIAL AND APPELLATE LEVELS, (COLLECTIVELY, "LOSSES") AND CLAIMS OF LOSSES, INCLUDING DUE TO BODILY INJURY, DISEASE, DEATH, OR PROPERTY DAMAGE (BUT EXCLUDING DAMAGE TO THE WORK ITSELF TO THE EXTENT COVERED BY BUILDERS RISK INSURANCE), MADE BY ANY THIRD PARTY, THAT IN ANY WAY ARISE OR RESULT FROM: (I) THE WORK; (II) CONTRACTOR'S ACTIVITIES OR THE ACTIVITIES OF ITS**

SUBCONTRACTORS, SUB-SUBCONTRACTORS, SUPPLIERS, OR OTHER PERSONS PERFORMING WORK; (III) OPERATIONS AT THE SITE; OR (IV) VIOLATION OF ANY APPLICABLE LAWS. THE FOREGOING INDEMNITY SHALL BE THE "CONTRACTOR'S GENERAL INDEMNIFICATION."

TO THE FULLEST EXTENT PERMITTED BY LAW, CONTRACTOR'S GENERAL INDEMNIFICATION SHALL INCLUDE LOSSES FOUNDED IN WHOLE OR IN PART ON THE ALLEGED NEGLIGENCE OR MISCONDUCT OF ANY OF THE INDEMNITEES; PROVIDED, HOWEVER, TO THE EXTENT THAT THE NEGLIGENCE OR MISCONDUCT OF THE INDEMNITEES IS ADJUDGED OR STIPULATED TO BE THE CAUSE OF THE LOSSES, THE INDEMNITEES SHALL BEAR ITS ADJUDGED OR STIPULATED PROPORTIONAL SHARE OF THOSE LOSSES AND SHALL PROMPTLY REIMBURSE CONTRACTOR FOR THEIR PROPORTIONAL SHARE OF THE COSTS AND EXPENSES OF DEFENSE.

8.2.2 Special Indemnity. **TO THE FULLEST EXTENT PERMITTED BY LAW AND SUBJECT TO THE STANDARD OF CARE, CONTRACTOR SHALL INDEMNIFY AND HOLD HARMLESS THE INDEMNITEES FROM ALL LOSSES AND CLAIMS OF LOSSES DUE TO CONTRACTOR'S MISCONDUCT, NEGLIGENCE, ERROR, OR OMISSION, MADE BY ANY THIRD PARTY, THAT IN ANY WAY ARISE OR RESULT FROM CONTRACTOR'S PROFESSIONAL SERVICES, INCLUDING CLAIMS OF PROFESSIONAL LIABILITY AND VIOLATION OF APPLICABLE LAWS. THE FOREGOING INDEMNITY SHALL BE THE "CONTRACTOR'S SPECIAL INDEMNIFICATION."**

8.2.3 Liens; Bond Claims. Contractor shall further indemnify, defend, and hold harmless, the Indemnitees, from all Losses and claims of Losses arising or resulting from liens and bonds of any kind asserted against the Project (individually, a "Payment Claim"), Project phase, or any part thereof, by any of Contractor's Subcontractors, Sub-subcontractors, Suppliers, and other Persons contributing to the Work, except for Payment Claims properly filed due to Owner's wrongful failure to make payments to Contractor.

8.2.4 Indemnitees' Control of Defense. Contractor's obligations in the Contract Documents to defend Indemnitees shall be performed by counsel approved by such Indemnitees, in their reasonable discretion. Indemnitees shall have the right to participate in direction of their defense and shall have the ultimate authority whether to settle any claim that may require any payment or admission of liability.

8.2.5 No Limitation. Contractor's indemnification obligations shall not be restricted by any limitation on the amount of damages, compensation, or benefits, payable by or for Contractor under applicable workers' compensation acts, disability benefit acts, or other employee benefits acts. Contractor expressly waives its immunity from suit from Owner under applicable workers' compensation acts, disability benefit acts, and other employee benefits acts.

8.2.6 Costs of Enforcement. Contractor shall reimburse all costs and expenses incurred by the Indemnitees to enforce Contractor's indemnification duties in the Contract Documents.

8.3. Insurance.

8.3.1 Contractor's Requisite Insurance. Contractor shall furnish and keep in force, and shall cause each Subcontractor to furnish and keep in force, the insurance required in *Exhibit N*. Contractor shall further furnish, keep in force, and file certificates evidencing coverage, such additional insurance required by Governmental Authorities having jurisdiction over the Work. To the fullest extent permitted by law, all such insurance requirements: (i) are minimum requirements intended to benefit the Indemnitees; (ii) will not be interpreted to limit Contractor's liability under the Contract Documents; and (iii) are independent of Contractor's other obligations under the Contract Documents. Contractor's failure to furnish, or failure to require Subcontractors to furnish, and Owner's failure to enforce, the Contract

Documents' required insurance, certificates, or endorsements, shall not waive the Contract Documents' requirements.

8.3.2 Subcontractor Default Insurance. Contractor may maintain Subcontractor default insurance and Owner shall have the right to accept or reject such insurance in Owner's sole discretion.

8.3.3 Owner-Controlled Insurance Program. Owner shall furnish for the benefit of the Project, the Site, and all Persons performing Work, Workers' Compensation, General Liability, Excess Liability, Builders Risk, Installation Floater, and or Pollution Liability insurance through an Owner-Controlled Insurance Program (an "OCIP"), subject to the coverages and according to the limits set forth in *Exhibit N*. Contractor and Subcontractors shall furnish and keep in force all other insurance required of them in *Exhibit N*. All Persons covered by the OCIP shall comply with the administrative and reporting requirements set forth in *Exhibit N*.

8.3.4 Intentionally Deleted.

8.3.5 **Contractor-Controlled Insurance Program**. In the event Contractor provides any of the insurance required by the Contract Documents through a Contractor-Controlled Insurance Program (a "CCIP"), Contractor shall deliver to Owner for review and approval a written description of the material features of the CCIP, including carriers, coverages, policy limits, and deductibles.

8.3.6 Notice Required. If the total of any potential claims against Contractor or any of its Subcontractors exceeds more than fifty percent (50%) of the available respective insurance coverage carried by Contractor or its Subcontractor, Contractor shall give to Owner prompt written notice. Thereafter, Owner shall have the right to require Contractor or Subcontractor, as the case may be, to increase its coverage in an amount Owner reasonably requires.

8.3.7 Evidence of Renewal. Not less than thirty (30) Days prior to the expiration of any insurance required by the Contract Documents due to its normal expiration or renewal date, Contractor shall furnish Owner with updated certificates of insurance and other necessary documentation, to clearly evidence continuation of all requisite coverage.

8.4. Bonds.

8.4.1 Contractor's Bonds. When a Contract Sum is One Hundred FiftyThousand and 00/100 Dollars ($150,000) or more, Contractor shall furnish and keep in effect at all times while the Contract Documents are in effect (a) a performance bond in sum equal to the Contract Sum and (b) a payment bond in sum equal to the Contract Sum. Notwithstanding the dollar thresholds state in this *Section*, Contractor shall furnish performance and payment bonds if otherwise required by the Contract Documents and in the amounts set forth in the Contract Documents. Any requisite performance bond shall cover all warranties and guarantees required by the Contract Documents.

8.4.2 Subcontractor Bonds. Owner and Contractor shall agree in writing to the bonding strategy and requirements of Subcontractors prior to any contracts pertaining to the Project between Contractor and any Subcontractors.

8.4.3 Public Works Bonds. Prior to signing the Contract Documents, Contractor shall file with the Oregon Construction Contractors Board, and maintain in full force and effect, the separate public works bond as and when required by Oregon Laws 2015, Chapter 279C, and OAR 839-025-0015. Contractor shall also include in every applicable Subcontract a provision requiring Subcontractor to file and maintain with the Oregon Construction Contractors Board, a separate public works bond as and when required, before starting Work. Contractor shall verify that each Subcontractor has complied with the requirements of this *Section* before permitting each such Subcontractor to begin Work.

8.4.4 Form of All Bonds. All Project bonds shall be in the forms attached as *Exhibit O* unless Owner otherwise approves in writing. All sureties guaranteeing performance or payment shall be (i) authorized to do business in the State of Oregon, (ii) have a rating of not less than "A" in the latest

version of A.M. Best & Company's Insurance Guide, (iii) an A.M. Best & Company financial size category of "X" or higher, and (iv) listed by, and in the net limit of, the United States Treasury Department as acceptable for bonding Federal projects. Contractor shall have no affiliation with the bonding agent or agency.

ARTICLE 9

PROTECTION OF LIFE AND PROPERTY

9.1. Safety Precautions and Protective Measures.

9.1.1 Contractor's Safety Plan. Contractor shall have overall responsibility and liability for Site, Project, and Work safety. Contractor shall develop, implement, and supervise all safety measures and programs at the Site and in connection with the Work, shall implement the safety and fire prevention program set forth in the Construction Plan, and shall require all Subcontractors and other Persons performing Work to conform to the same. Contractor shall review and recommend appropriate changes to, but shall not have direct control over, each Subcontractor's safety program. As such, Contractor's review and recommendations shall not relieve Subcontractors of their responsibility for the safety of persons and property, and for compliance with all Applicable Laws.

9.1.2 Safeguards. Contractor shall erect and maintain, as required by existing conditions and the progress of the Work, all reasonable safeguards, including posting danger signs and other warnings against hazards, promulgating safety regulations, and notifying affected Persons.

.1 Contractor shall take all reasonable safety precautions, protective measures, and care to prevent damage, injury, and loss to: (i) all Persons on, about, and adjacent to the Site and in locations with stored Materials; (ii) all Work under the custody or control of Contractor, Subcontractors, or Sub-subcontractors, whether completed, in progress, or stored; and (iii) work of Owner and Owner's Separate Contractors; (iv) existing Site landscaping and plant life not designated for removal in the Contract Documents.

.2 Without limiting Contractor's responsibility for Site and Work safety, **Contractor shall comply with all of Owner's Standard Requirements, attached as *Exhibit I,* and** Owner Parties shall have the right, but not the obligation, to review and approve Contractor's safety measures and programs.

.3 Contractor's safety practices and protection of persons and property shall be industry best practices, conform to the Contract Documents, and comply with all Applicable Laws, including all applicable regulatory and advisory agency safety standards.

9.1.3 Adjacent Property and Work. Contractor shall not enter upon property that is private or adjacent to the Site without first obtaining permission. Contractor shall be responsible for and use every precaution to preserve all public and private property adjacent to the Work, including trees, shrubs, lawns, walks, pavement, roadways, structures, and utilities. Contractor shall be responsible for protection of adjacent work areas, including other work, brought about by activities, equipment, labor, utilities, vehicles, or materials on the Site.

9.1.4 Damages. Contractor shall promptly remedy all damage and loss (other than damage or loss covered by property insurance required by the Contract Documents) to any property referred to above, caused in whole or in part by Contractor, Subcontractors, Sub-subcontractors, or by Person for whose acts they may be liable.

9.1.5 Site Safety Supervisor. Contractor shall designate and keep at the Site a responsible and qualified member of Contractor's organization who shall manage Contractor's safety program. Contractor shall report to Owner the name, position, and direct contact information, of the person so designated.

9.2. **Emergencies**. In any emergency affecting the safety of persons or property, Contractor shall act in its sound discretion to prevent threatened damage, injury, or loss. Contractor's Claims for additional compensation or extension of time as a result of an emergency shall be determined in accordance with *Article 12* of these General Conditions.

9.3. **Reporting Requirements**. Following an emergency or occurrence involving personal injury or property damage, Contractor shall furnish Owner with, not more than three (3) Days after an incident, the full written details, photographs, and statements of witnesses, of each incident. In addition, following an emergency or an occurrence involving serious personal injuries, serious property damage, or death, Contractor shall immediately report the same to Owner by telephone or messenger. Contractor shall again promptly inform Owner of the ultimate disposition of any occurrences as set forth above, following their conclusion.

9.4. **Hazardous Materials**. Contractor shall not use, in connection with the Work, any Hazardous Materials (defined below) in a manner that poses unreasonable safety risks or violates Applicable Laws. This *Section* shall not prohibit Contractor from using any item specified in the Contract Documents unless Contractor knows it violates Applicable Laws, in which case Contractor shall notify Owner Parties in writing so that Owner may issue an appropriate Change Order.

9.4.1 Definition. "Hazardous Materials" shall mean any hazardous waste, toxic substance, radioactive material, asbestos containing material, petroleum product, or related materials including substances defined as "hazardous substances," "toxic substances," and similar designations in any Applicable Laws, including without limitation, in the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, 42 U.S.C. Sec. 9061 et seq.; Hazardous Materials Transportation Act, as amended, 49 U.S.C. Sec. 1802 et seq.; the Resource Conservation and Recovery Act, as amended, 42 U.S.C. Sec. 6901 et seq.; and the corresponding regulations (as amended) issued pursuant to these acts.

9.4.2 Existing Conditions. Unless Hazardous Materials disposition is specifically a part of the Contract Documents or was necessitated by that actions of Contractor, Subcontractors, Sub-subcontractors, or the acts or omissions of Persons' for whom they are liable, Contractor shall not be responsible for Hazardous Materials existing at the Site prior to commencement of Work (the "Preexisting Hazardous Materials"). If Contractor reasonably suspects it has encountered Preexisting Hazardous Materials, Contractor shall, immediately upon recognizing the condition, have the right to stop Work in the affected area, and shall immediately notify Owner Parties of the same.

9.4.3 Owner Actions Upon Notice. Promptly after receiving notice of reasonably suspected Preexisting Hazardous Materials, Owner Parties shall take reasonable measures to ensure that the Preexisting Hazardous Materials are remediated. Specifically, Owner shall retain qualified independent experts to (a) determine if the area of concern does contain a Hazardous Material, and (b) prescribe remedial measures to render Hazardous Material harmless as necessary. Contractor shall resume Work in the affected area only upon Owner and Contractor's written agreement.

9.5. **Contractor's Responsibility**.

9.5.1 Environmental Protection. Contractor shall at all times direct its activities and the activities of its Subcontractors, Sub-subcontractors, Suppliers, and other Persons performing Work in and around the Site to minimize adverse effects on the environment.

Contractor shall, at all times: (i) at no additional cost to Owner, properly handle and dispose of all environmental pollutants and hazardous substances brought onto the Site during performance of the Work, to the satisfaction of Owner and Government Authorities having jurisdiction, and in a manner that complies with Applicable Laws; (ii) be responsible for all spills, releases, discharges, or leaks of environmental pollutants, brought to the Site during performance of the Work; and (iii) promptly clean up and remediate, without cost to the Owner, such spills, releases, discharges, and leaks, to Owner's satisfaction and in compliance with Applicable Laws.

9.5.2 Reporting. Contractor shall report all releases of Hazardous Materials as required by Applicable Laws, including 40 CFR Part 302, Table 302.4 and OAR 340-142-0050.

In addition to following the emergency procedures set forth in *Sections 9.2* and *9.3* above, Contractor shall immediately report to Owner Parties by telephone all releases of Hazardous Materials introduced to the Site during performance of the Work. A written follow-up report shall be submitted to Owner Parties within forty-eight (48) hours of the initial report, and shall contain at a minimum: (i) a description of items released including identity, quantity, manifest numbers; (ii) whether amounts of items released is EPA/DEQ reportable, and, if so, when Contractor so reported; (iii) exact time and location of each release, including a description of the area involved; (iv) Contractor's containment procedures initiated; (v) a summary of communications about the release between Contractor and officials other than Owner; and (vi) a description of cleanup procedures employed or to be employed, including disposal locations.

9.5.3 Indemnity. **TO THE FULLEST EXTENT PERMITTED BY LAW, INCLUDING ORS 30.140, CONTRACTOR SHALL INDEMNIFY, DEFEND, AND HOLD HARMLESS, THE INDEMNITEES FROM ALL LOSSES AND CLAIMS OF LOSSES, MADE BY ANY THIRD PARTY, THAT IN ANY WAY ARISE OR RESULT FROM HAZARDOUS MATERIALS THAT CONTRACTOR, ITS SUBCONTRACTORS, OR ANY PERSON FOR WHOSE ACTS THEY MAY BE LIABLE, INTRODUCE TO THE SITE.**

The foregoing indemnity shall not apply to Hazardous Materials that Contractor or its Subcontractors introduce to the Site in accordance with the Contract Documents and in compliance with all Applicable Laws.

9.6. No Limitation. Nothing in this *Article 9* shall limit Contractor's responsibility for obtaining insurance coverage required under the Contract Documents, and Contractor shall take no action that would void or impair such coverage.

ARTICLE 10

ALLOWANCES; SUBSTITUTIONS; CHANGES

10.1. Allowances. Contractor shall include in the Contract Sum all Allowances stated in the Contract Documents and their Associated Costs (defined below). Items included in Allowances shall be furnished and installed for the amounts and by Persons as Owner Parties direct. Unless Owner Parties request otherwise, Contractor shall provide to Owner Parties for approval, at their request, a proposed fixed lump-sum price for any Allowance, including its Associated Costs, prior to its performance.

Unless otherwise set forth in the Contract Documents: (i) when finally reconciled, Allowances shall cover Contractor's cost of Materials delivered to the Site, and all applicable Taxes, less applicable trade discounts; (ii) Contractor's costs for unloading and handling at the Site, labor, installation costs, overhead, profit, and other expenses, contemplated for the Allowance (collectively, the "Associated Costs") shall be included in the Contract Sum but not in the Allowance; and (iii) whenever Contractor's costs are more than or less than an Allowance, the Contract Sum shall be adjusted accordingly by Change Order in the amount of the difference between the amount of the original Allowance item and its actual cost including changes, if any, to Associated Costs.

10.2. Substitutions. When more than one product or process is specified by the Contract Documents as being acceptable (including the designation "or equal"), Contractor shall have the option of using any such specified product. When only one product or process is specified, Contractor shall not be permitted a Substitution except as set forth in this *Section*.

10.2.1 Requested Substitutions shall meet the standards, required function, size, type, appearance, and quality, of Materials they are intended to supplant. In the event Contractor wishes to request a Substitution, Contractor shall first submit a written request for Owner Parties' approval.

Requests for Substitutions shall be timely, fully documented, and will be accompanied by evidence about the requested Substitution, including: (i) its quality and serviceability; (ii) changes in details and construction of related Work; (iii) pertinent drawings, specifications, samples, performance data; (iv) its design and artistic effect; and (v) changes to the Contract Sum. By submitting a Substitution proposal, Contractor represents that the Substitution meets or exceeds the standards, qualities, guarantees, and warranties, of the specified item being substituted, except to the extent Contractor disclaims in writing within its proposal.

10.2.2 Substitutions will only be considered under the following circumstances: (i) when a product or process specified in the Contract Documents is discontinued and not reasonably available; (ii) when a requested Substitution, in Contractor's and Owner Parties' opinion, is in Owner's best interest; or (iii) when Contractor can demonstrate that the price of the specified product or process is unreasonably inflated and Substitution will be significantly less expensive. Owner Parties will make recommendations to Owner regarding requested Substitutions, and Owner may, in its discretion, reject or approve the same.

Approved Substitutions that result in a change to the Contract Sum shall be accompanied by a Change Order in the amount of the difference in the Contract Sum between the specified product or process and its Substitution.

10.3. <u>Changes</u>.

10.3.1 <u>Minor Changes in the Work</u>. Owner Parties shall have authority to order minor changes in the Work that shall be effective and bind Contractor upon Owner Parties' written order. Contractor shall promptly carry out all written orders of minor changes in the Work. In the event Contractor reasonably believes a change in the Work is not minor, and Contractor will be harmed without adjustment to the Contract Sum or Contract Time, Contractor shall immediately notify Owner Parties and shall not proceed to implement the change in the Work. If Owner Parties disagree that Contractor is entitled to an adjustment to the Contract Sum or the Contract Time, Contractor shall proceed with the ordered change in the Work and may submit a Claim. However, if Contractor performs the change in the Work set forth in the Owner Parties' order without prior notice that it believes such change will affect the Contract Sum or Contract Time, Contractor waives any such Claim.

10.3.2 <u>Change Orders</u>. All Change Orders shall be in the form attached as *Exhibit P*, shall be priced in accordance with this *Article 10*, and shall contain the details of the changes to the scope of Work, Contract Time, Contract Sum, and any related adjustments to the Contract Documents. Expect as set forth in this *Article 10*, only a Change Order shall authorize a change to: (i) the scope of the Work, (ii) the Contract Time or a significant modification to the schedule of performance of the Work or the Project, or (iii) the Contract Sum or Contractor's compensation. As such, Contractor shall have no Claim for Work performed that would have been subject to, but for which Contractor failed to request, a Change Order.

10.3.3 <u>Owner-Directed Changes</u>. Owner Parties may order Contractor to price and determine time impacts of, at any time, a change in the scope of Work, by submitting to Contractor a reasonably-detailed written statement setting forth the nature of the change. If Contractor determines in good faith that Owner Parties' change will (a) increase or decrease the Contract Sum or (b) impact the dates for Substantial Completion set forth in the applicable Construction Schedule, Contractor shall promptly furnish Owner Parties with detailed information setting forth the cost and time impacts of the change in accordance with *Section 10.3* of these General Conditions. If Owner elects to order the changed Work, it shall issue to Contractor a Change Order ordering and authorizing Contractor to proceed with the changes, as agreed. Contractor shall not commence such a change until Owner has issued a Change Order, except in an emergency endangering life or property, as set forth in *Section 9.2* of these General Conditions.

10.3.4 Changes Other than Owner Directed. If Contractor encounters at the Site (a) concealed physical conditions materially differing from those indicated in the Contract Documents or (b)unknown and unforeseen physical conditions of unusual nature, materially differing from those ordinarily found to exist in the vicinity of the Site or as otherwise provided for in the Contract Documents, and such differing conditions will reasonably harm Contractor, Contractor shall give to Owner Parties notice before such conditions are further disturbed and in no event later than three (3) Days after their discovery. Owner Parties will promptly investigate purported differing conditions to determine if in fact they materially differ from those ordinarily found near the Site or as provided in the Contract Documents.

10.3.5 Owner Parties' Determination. Owner Parties shall be entitled to review Contractor's Claims for differing Site conditions as set forth in *Section 10.3.4* above, and for changes due to Unavoidable Delay as set forth in *Section 7.2.4* of these General Conditions. If, after investigation, Owner Parties agree that a Change Order is appropriate under the circumstances, Contractor will be entitled to adjustment to the Contract Sum, Contract Time, or schedule of performance of the Work, as the case may be, and as agreed to by Owner and Contractor. If a request for Change Order includes requests from Subcontractors, Sub-subcontractors, Suppliers, or other Persons performing Work, Contractor shall analyze and evaluate the merits of such requests prior to including them in Contractor's submission to Owner Parties. By submitting such requests, Contractor represents they are accurate and appropriate.

In any event, if Owner Parties disagree that Contractor in entitled to a Change Order under the circumstances, Owner Parties shall notify Contractor in writing, stating the reasons for disagreement. If Contractor wishes to dispute Owner Parties' determination, Contractor shall have a Claim. However, Owner shall in no event approve a Change Order because of missed Work scope or a lack of coordination in the execution or bidding of the Work.

All Claims due to changes shall proceed in accordance with *Article 12*.

10.3.6 Requisite Performance of Changes. In the event Owner refuses to issue a Contractor-requested Change Order or Owner and Contractor fail to agree to the terms of a Change Order, Owner Parties shall have the right to issue a Construction Change Directive. Upon receiving a Construction Change Directive, Contractor shall proceed to perform such changed Work and Owner shall pay Contractor on a time and material basis in accordance with *Section 10.3.7* below. Owner Parties and Contractor shall continue to make good faith efforts to agree to the terms of a Change Order for the Work of the Construction Change Directive. Change Orders may be issued for all or any part of a Construction Change Directive. However, if Owner and Contractor cannot agree to one or more Change Orders for all of the Work of a Construction Change Directive, Contractor shall have a Claim for that Work executed but not included in a Change Order.

10.3.7 Price and Schedule Adjustments. Unless Owner and Contractor agree in writing, all monetary adjustments included in Change Orders and Construction Change Directives, whether cost or credit to Owner, shall be calculated using the terms and figures of *Exhibit Q* and other unit prices set forth in the Contract Documents. However, if quantities of Materials and labor originally contemplated in a unit price significantly differ from those in a Change Order such that a unit price will cause substantial inequity to Owner or Contractor, that unit price shall be equitably adjusted.

When submitting a request for, or responding to, a Change Order, Contractor shall furnish Owner with detailed estimates of proposed adjustment to the Contract Time, changes to the schedule of performance of the Work or the Project, and the Contract Sum or Contractor's compensation, as the case may be. As applicable, each approved Change Order shall incorporate an accurate revised Schedule of Values and an accurate revised Construction Schedule.

10.3.8 Accounting. Contractor and Subcontractors impacted by a Change Order or Construction Change Directive shall maintain itemized accounts of all charges and credits due to changes

in the Work as a result of all such changes. Such itemized accounts shall be open to Owner Parties' inspection.

10.3.9 Owner-Directed Acceleration; Constructive Acceleration. The Owner shall have the right to accelerate the completion date of the Work by Change Order, which may require the use of overtime. Additionally, Owner shall have the right to refuse to grant to Contractor an extension of time to meet the completion milestones set forth in the Design Schedule, Construction Schedule, or Project Schedule, even if Contractor is entitled to an extension pursuant to the Contract Documents. In the event Owner accelerates performance of the Work, the Contract Sum shall be adjusted in accordance with *Section 10.3.3* above, but Contractor shall not be entitled to any other compensation or recovery. Prior to commencing the acceleration of Work, Contractor shall submit to Owner Parties for approval its written plan to cost efficiently execute such acceleration.

10.3.10 No Additional Claims. Neither Contractor nor Subcontractors shall have Claims for impact costs due to a Change Order. All money and time impacts associated with a Change Order shall be included in that Change Order. Contractor shall not be entitled to and shall not request, a Change Order, and shall make no Claims, after Owner Parties receive Contractor's final Application for Payment that includes such changed Work.

ARTICLE 11

WORK ASSURANCES AND GUARANTEES

11.1. Design Warranty. Subject to the Standard of Care, Contractor warrants that the Services will conform to the Contract Documents' requirements, Applicable Laws and lawful orders of Governmental Authorities, and will be free from defects. Owner may consider Services not conforming to these requirements defective. If any of the Services are contrary to the Contract Documents' requirements, Applicable Laws and lawful orders of Governmental Authorities, Contractor shall promptly correct and cause such Services to conform to the same and all corrective measures shall be at Contractor's expense.

11.2. Uncovering of Work.

11.2.1 Wrongful Covering. If any portion of Work is covered contrary to Owner Parties' written request or contrary to the Contract Documents' requirements, Contractor shall, upon request, uncover such Work for Owner Parties' inspection and shall recover and replace the same upon Owner Parties' approval. All uncovering and recovering under this *Section* shall be at Contractor's expense.

11.2.2 Requested Uncovering. If Owner Parties have not specifically requested in writing any portion of Work remain uncovered for inspection, Owner Parties may still require that Contractor promptly uncover such Work. Following uncovering and Owner Parties' review, if such Work is in accordance with the Contract Documents, then Owner shall pay the cost of uncovering and replacement by Change Order. However, if such Work is Defective Work, Contractor shall pay all such costs.

11.3. Correction of Work.

11.3.1 Contractor's Obligation. Prior to Substantial Completion of each Deliverable Portion of Work and for a period of one (1) year following the later of: (i) Substantial Completion of each Deliverable Portion of Work; (ii) the date for commencement of warranties in accordance with the Contract Documents; or (iii) such longer periods of time contained in the Contract Documents' specific warranties (collectively, the "Defective Work Warranty"), Contractor shall promptly remove from the Site and correct and repair all Defective Work, whether completed or in progress. Costs of removing and correcting Defective Work, including additional testing and inspections, uncovering, replacement, and

recovering, and associated compensation for the Owner Parties' additional services, shall be at Contractor's expense.

11.3.2 Opportunity to Cure. If Owner Parties become aware of Defective Work they will promptly deliver to Contractor written notice of the same and shall provide Contractor reasonable opportunity to cure the Defective Work. However, if Contractor does not fully perform its obligations under this *Section* within thirty (30) Days after it receives Owner Parties' written notice of Defective Work, Owner shall have a Claim and may cause Contractor's obligations to be performed at Contractor's expense. If Owner chooses to repair such Defective Work using Owner's own forces, Contractor shall pay to Owner one and one half (1-1/2) times the standard hourly rate of Owner's forces used to perform the work, plus related overhead and direct non-salary costs. If Owner completes the repairs using Owner's Separate Contractor, Contractor shall pay to Owner the direct expense billed by Owner's Separate Contractor for its work plus the direct salary costs, related overhead, and direct non-salary expenses, of Owner, for monitoring Owner's Separate Contractor's work. If any of these expenses cause the Contract Sum to be exceeded, the excess shall be payable to Owner from Contractor on demand, or deducted from amounts to be paid by Owner to Contractor.

11.3.3 Term Upon Correction or Completion. The one (1) year Defective Work Warranty shall be extended for those portions of Work first performed after Substantial Completion of each Deliverable Portion of Work and for the corrective Work performed pursuant to this *Section* by the longer of (a) the period of time between Substantial Completion of each Deliverable Portion of Work and the actual completion or correction of that portion of the Work or (b) the period of time prescribed by law or by the terms of any applicable special warranty or guarantee under the Contract Documents.

11.3.4 Equitable Adjustment. In the event Owner does not require Contractor to remove or correct any Defective Work, Owner shall be entitled to an equitable deduction to the Contract Sum for the reduced value of that Defective Work. Owner and Contractor shall agree upon a deduction to the Contract Sum that is equitable and all such deductions shall be evidenced by Change Order.

11.3.5 No Limitation. The one (1) year Defective Work Warranty neither limits the time within which Owner may enforce Contractor's obligation to comply with the Contract Documents, nor the time within which Owner may commence proceedings pertaining to Contractor's obligations under the Contract Documents. The expiration of the Defective Work Warranty, and expiration of any of Contractor's other guarantees or obligations to correct Defective Work, shall not relieve Contractor of the obligation to correct, at its own expense, latent defects in the Work.

Nothing contained in this *Article 11* shall establish a period of limitation for any warranty obligation under the Contract Documents (other than the Defective Work Warranty) or modify a statute of limitations or repose.

11.3.6 On-Call. During the first three (3) months following Substantial Completion of each Deliverable Portion of Work, Contractor shall have appropriate personnel on call to respond rapidly to system emergencies, all as agreed to by Contractor and Owner in *Exhibit* __ (the "On-Call Parameters").

11.3.7 **Warranties**. Warranties arising from this *Article 11* and all other warranties and guarantees required by the Contract Documents (collectively, the "Warranties") that are applicable to a Deliverable Portion of Work shall commence upon Substantial Completion of such Deliverable Portion of Work, and shall run directly to Owner or be fully assignable to Owner and its designee. All such Warranties shall be assigned to Owner or, at Owner's option, its designee. Contractor shall furnish Owner with documentation necessary to enable Owner to obtain the benefit of all Warranties. Contractor shall assist Owner to enforce its long-term warranties or guaranties. The Warranties shall be in addition to and not in limitation of any other warranty or remedy at law or in equity.

ARTICLE 12

CLAIMS

12.1. Notice.

12.1.1 Initial Notice. If Owner has a Claim, Owner shall promptly notice Contractor of such Claim in writing, setting forth the known details and support for the Claim. If Contractor has a Claim, Contractor shall furnish Owner with a detailed, supported, written notice, setting forth the known or estimated length of any Delay and any known or estimated monetary impacts, due to such Claim. Contractor shall deliver to Owner such notice no later than seven (7) Days following actual knowledge of the event giving rise to the Claim. For purposes of Owner Parties' denial of any of Contractor's requests to modify any terms of the Contract Documents (whether Contract Sum, Contract Time, or otherwise) in accordance with Contractor's rights to make such requests under the Contract Documents, the event giving rise to the Claim (and thus the start of the seven (7) Day period) shall be Contractor's receipt of Owner Parties' written denial.

If it is impracticable to specify the actual length of a delay or monetary amount of a Claim at the time notice is required, the claimant shall provide estimates and periodic supplemental notices to keep the nonclaimant party informed of any change and other relevant information while the events giving rise to the Claim continue.

12.1.2 Formal Claim Process. Promptly following notice of the Claim as set forth above, Contractor's on-Site senior project manager (designated in *Section 4.3.3* of these General Conditions) and Owner Parties' project manager, shall work cooperatively to resolve the Claim (the "Preliminary Claim"). However, if three (3) weeks after the notice of Claim has been received by the non-claimant, Contractor's and Owner Parties' project managers believe the Preliminary Claim will not be resolved, the Claim shall be submitted to the Major Claim (defined below) process.

All Claims not resolved by the Preliminary Claim process shall be "Major Claims." Owner shall designate **a neutral third party**, with a substantial understanding of and experience in the design and construction industry, to review all Claims (the "Claims Examiner") to hear and decide all Major Claims. Within thirty (30) Days after the initial notice of a Major Claim, the claimant shall submit to the Claims Examiner and non-claimant a complete and detailed written description of its Major Claim including: (i) a detailed, factual statement of the basis of the Claim; (ii) pertinent dates of the events giving rise to the Claim; (iii) Contract Documents provisions that support or allow the Claim; (iv) copies of all documents which support the Claim; (v) the total monetary and time impacts of the Claim, broken down to clearly demonstrate its impact on the Contract Sum, Contractor's compensation, the Contract Time, and schedules of performance of the Work (collectively, the "Detailed Claim"). Within ten (10) Days of receiving the Detailed Claim, the non-claimant shall have the right to submit to the Claims Examiner a formal response to the Detailed Claim, confirming or rebutting the allegations and other details set forth in that Detailed Claim.

12.1.3 Indirect Claims. If a Contractor's Claim involves Work of Subcontractors, Sub-subcontractors, Suppliers, or other Persons performing work on their behalf, Contractor shall analyze and evaluate the merits of such Claim prior to noticing Owner of the same and by giving such notice, represents such Claim is accurate and appropriate. Owner Parties will not consider direct claims from Subcontractors, Sub-subcontractors, Suppliers, and others not a party to the Contract Documents.

12.1.4 Limited Claims for Damages. Neither Contractor nor Owner shall have a Claim for damages to property or injury arising from an act, omission, or peril, insured pursuant to any policy carried by the party suffering such damage. Furthermore, such a Claim shall not be assignable or the subject of a subrogation action by any third party. To the extent a party suffering damage receives

insurance proceeds for damages that otherwise could give rise to a Claim, the other party shall be released from liability, for such damages.

12.1.5 Waiver. Unless a notice of Claim and the Formal Claim is made in accordance with the time requirements of this *Section*, it shall be deemed waived.

12.1.6 Continuation of Work. Unless otherwise directed by Owner Parties, Contractor shall continue to diligently prosecute the Work while any Claim is pending.

12.2. Formal Claim Review.

12.2.1 Initial Decision. The Claims Examiner will review all Major Claims and take one or more of the following preliminary actions within fifteen (15) Days of receipt of a Detailed Claim: (i) request additional supporting information from the claimant; (ii) inform the Contractor and Owner in writing of the time required for adequate review and response; (iii) reject the Claim in whole or in part and identify the reasons for rejection; (iv) based on unit prices identified in *Exhibit Q* and recommend approval of all or part of the Claim; or (v) propose an alternate resolution. In any event, notwithstanding anything to the contrary contained in this *Article 12*, if the Claims Examiner has not issued its decision within thirty (30) Days of the Detailed Claim being filed, that Claim shall be subject to appeal and submitted to non-binding mediation all as set forth below.

12.2.2 Appeal. The Claims Examiner's decision shall be final and binding unless appealed by Contractor's or Owner's written notice to the other, setting forth those portions of the Claims Examiner's decision being appealed, within fifteen (15) Days of all parties' receipt of such decision. Owner and Contractor hereby acknowledge and agree mediator, whether temporary or presiding, shall not be subject to subpoena or otherwise asked or required to produce records, notes, or work product, or asked or required to testify in any proceedings as to information disclosed or representations made during the course of mediation, except to the extent required by law.

12.2.3 Mediation. A proper and timely appeal of the Claims Examiner's decision shall be submitted to non-binding mediation within fifteen (15) Days following all parties' receipt of the notice of appeal and such appeal shall be reviewed by the mediator *de novo*. The presiding mediator shall be an individual mutually acceptable to Owner and Contractor, unless the parties cannot agree, in which case each party shall select a temporary mediator and the temporary mediators shall jointly select a presiding mediator. Owner and Contractor shall pay their own costs and expenses and the cost of the mediator shall be split equally between the two parties. The schedule, time and place for mediation will be mutually acceptable to Owner and Contractor, unless the parties cannot agree, in which case the mediation venue shall be at or in close proximity to the Site.

.1 Owner and Contractor acknowledge and agree that, subject to Claim Preservation as set forth below, participation in mediation shall be a prerequisite to litigation of any Contract Documents disputes. Owner and Contractor shall use best efforts in good faith to resolve through the mediation process all Major Claims within sixty (60) Days of the commencement of such mediation (the "Mediation Period"). However, if the presiding mediator fails to issue its decision on one or more of the issues presented within ninety (90) Days of the commencement of such mediation, the parties shall have the option to file a lawsuit in accordance with *Section 12.2.4* below and adjudicate those undecided issues, notwithstanding the requirement to mediate as a condition precedent to filing suit. Additionally, if a lawsuit must be filed within the Mediation Period in order to preserve a cause of action (a "Claim Preservation"), Owner and Contractor agree that they will nevertheless proceed diligently to mediate the Claim to its conclusion prior to actively prosecuting the lawsuit. As such, Owner and Contractor shall seek from the Court presiding over the Claim Preservation lawsuit such stays and extensions, including the filing of an answer, as may be necessary to mediate effectively. Further, if during the Mediation Period Owner and Contractor settle any issues, the plaintiff in the Preservation Claim

lawsuit shall promptly cause the Court to enter a stipulated general judgment of dismissal with prejudice, or other appropriate order, limiting the remaining scope of litigation.

.2 The parties agree to comply with Owner's Standard Requirements, which may include but are not limited to confidentiality of mediation, and shall promptly sign all documents necessary to give effect to such requirements.

12.2.4 Litigation. Major Claims not resolved by mediation during the Mediation Period shall be submitted to the Benton County Oregon Circuit Court and the Parties hereby consent to the jurisdiction of the same and waive any objection which it may now or later have to the laying of venue of any action or proceeding in such court; provided, however, notwithstanding the foregoing, if a legal action or proceeding must be brought in a federal forum, the Party bringing such action or proceeding shall do so in the United States District Court for the District of Oregon. This paragraph shall not be construed to (a) authorize Contractor to bring a legal action or proceeding against Owner in a federal forum except to the extent Congress has validly abrogated OSU's sovereign immunity or (b) waive any form of Owner's immunity, including sovereign immunity and immunity based on the Eleventh Amendment to the United States Constitution.

Owner and Contractor hereby acknowledge and agree mediator, whether temporary or presiding, shall not be subject to subpoena or otherwise asked or required to produce records, notes, or work product, or asked or required to testify in any proceedings as to information disclosed or representations made during the course of mediation, except to the extent required by law. [Discussion point – waive jury trial?]

12.3. No Claims for Consequential Damages.

12.3.1 Consequential Damages Waived. Contractor and Owner each waive Claims against the other for consequential damages arising out of the Contract Documents, including (a) Owner's damages for rental expenses, loss of use, lost opportunity, loss of income, lost profit, interest from financing, and damage to reputation, and (b) Contractor's damages for principal office expenses, lost opportunity, interest from financing, damage to reputation, and loss of profit except anticipated profit arising directly from the Work and earned by Contractor in accordance with the Contract Documents.

12.3.2 Limitations. Nothing in this *Section 12.3* shall preclude recovery of: (i) Liquidated Damages in accordance with the Contract Documents; (ii) third-party claims, Claims, and indemnity requirements of *Section 8.2* of these General Conditions; (iii) Claims, damages, costs, or expenses due to violations of Applicable Laws; (iv) Claims, damages, costs, or expenses relating to fraud, gross negligence, or willful misconduct; (v) Claims, damages, costs, or expenses covered by any insurance policy; (vi) Claims, damages, costs, or expenses due to Contractor's refusal to perform in accordance with the Contract Documents; or (vii) breach of any intellectual property or confidentiality obligations.

ARTICLE 13

TERMINATION

13.1. Suspension.

13.1.1 Owner's Right to Suspend. Owner may, with or without cause, furnish Contractor with a written order to suspend the Work in whole or in part for such period of time as Owner may determine in its sole discretion, but not to exceed ninety (90) Days. Upon receipt of such an order to suspend, Contractor shall promptly cease all Work, except to the extent Owner's order also requires Contractor to protect completed and partially-completed Work or to maintain during the period of suspension the Work protection of the Work, maintenance of access, protection of stored Materials, maintenance of temporary facilities, and general cleaning. If Owner's suspension of the Work exceeds ninety (90) Days, and Owner re-engages Contractor to commence the Work once again with written

notice, Contractor shall be entitled to an equitable adjustment to the Contract Sum for the length of time exceeding ninety (90) days. No such suspension of the Work will be the basis of a Claim except for Cost of the Work directly relating to maintenance of the Site during such suspension.

13.2. Termination.

13.2.1 Owner's Right to Perform. If Contractor fails to perform any if its obligations under the Contract Documents, then Owner may, after five (5) Days' prior written notice, during which time Contractor continues to fail to diligently pursue performance of any such breached obligation and without prejudice to any other remedy Owner may have at law or in equity, cause Contractor's breached obligations to be completed by others. All costs and expenses Owner incurs addressing Contractor's failure to perform under this *Section* shall become Contractor's liability to Owner payable upon demand and subject to offset against the Contract Sum. If the balance of the Contract Sum is not sufficient to cover such offset amount, Contractor shall immediately pay to Owner the difference. However, in no event shall Owner's actions under this *Section* be deemed a termination of the Agreement.

13.2.2 Funds Available and Authorized. If Owner fails to receive funding, appropriations, allocations, or other expenditure authority, as contemplated by Owner's budget, Owner may terminate the Contract Documents based on its assessment and ranking of the policy objectives explicit or implicit in Owner's budget, and such termination shall be deemed and proceed according to Owner's termination for convenience (below).

13.2.3 Owner's Termination for Convenience. Owner may, at any time and without cause, terminate the Agreement, in whole or in part, by delivering to Contractor at least ten (10) Days in advance, a notice of termination for convenience specifying the extent and the effective date of termination. Upon such date of termination, Contractor shall (a) immediately and peacefully surrender possession of the Site and all Materials for which the Contractor received progress payments, and (b) assign to Owner those Subcontracts that Owner requests. Under those Subcontracts to which Owner elects to take assignment, Owner shall assume Contractor's obligations that accrue after the date of termination. Contractor shall take such action and shall execute such documents as Owner may reasonably require for such assignments to be effective and shall not enter agreements that prevent such assignment.

Following termination, Contractor shall only be entitled to (a) that portion of the Contract Sum earned up until the effective date of termination and (b) reasonable actual demobilization costs.

13.2.4 Owner's Termination for Cause. If a Defaults occurs at any time during the Project and Contractor fails after five (5) Days written notice to commence and diligently pursue a cure to such Default or fails to actually cure the Default within a reasonable period of time, Owner may terminate the Agreement for cause and take possession of the Site and all Materials on the Site, including those Contractor owns. Owner may subsequently finish the Work by whatever reasonable methods are expedient and Contractor shall not be entitled to receive any further payment until the Work is finished. However, in the event of such a termination for Default, Contractor shall not be relieved from its obligations under the Contract Documents.

If Owner completes the Work and the unpaid balance of the Contract Sum exceeds Owner's cost and expense to finish the Work, including its consequential damages and professional services fees, Contractor shall be compensated for the Work it actually performed. However, if Owner's costs and expenses to complete the Work, including its consequential damages and professional services fees, exceed the unpaid balance of the Contract Sum, Contractor shall pay to Owner the difference upon demand. This *Section* shall survive termination of the Agreement.

13.2.5 Termination Deemed Termination for Convenience. If a court of competent jurisdiction, mediator, or arbitrator, as the case may be, determines that Owner's termination for cause was wrongful, such termination shall be deemed a termination for convenience pursuant to *Section 13.2.3* of these General Conditions and Contractor's remedy shall be limited to the provisions of that *Section*.

13.2.6 Transfer of Documents. As directed by Owner, Contractor shall, upon any termination under this *Article 13*, transfer title and deliver to the Owner all Record Documents, information, and other property, that is reasonably necessary to effectuate completion of the Work or assignment of subcontracts, or that Owner Parties may otherwise reasonably request.

13.2.7 Contractor's Termination. If Owner fails to pay to Contractor within forty-five (45) Days after due any undisputed amounts under the Agreement, Contractor may, after fifteen (15) additional Days' written notice to Owner during which time Owner continues to fail to make such payment, terminate the Agreement. If Contractor properly terminates for cause under this *Section*, it may recover from Owner that portion of the Contract Sum earned prior to the date of termination. Contractor hereby waives any other right of recovery for damages due to termination under this *Section*, including anticipated profits (for the balance of the un-executed Work) and consequential damages.

ARTICLE 14

MISCELLANEOUS

14.1. Use of Drawings and Specifications; Ownership. The Drawings, Specifications, and other documents prepared by or for Owner Parties, are Instruments of Service. Contractor may retain one record set of such Instruments of Service but Contractor, Subcontractors, Sub-subcontractors, and other Persons performing Work shall have no claim to or ownership of them and shall not use them for any purpose other than for the Work. Unless otherwise indicated, Owner shall be deemed the author and owner of all Project Instruments of Service.

Contractor, Subcontractors, Sub-subcontractors and Suppliers are granted a limited license to use and reproduce applicable portions of the Instruments of Service to aid in the execution of their Work. All such copies made under this license shall bear any statutory copyright notice found on the originals. All such copies, except Contractor's record set, shall be returned to Owner upon request and upon completion of the Work.

14.2. Interest. Interest on payments past due and owing between parties to the Contract Documents shall be at the rate of two thirds of one percent (0.667%) per month.

14.3. Independent Contractor Status. The services and work to be performed under the Contract Documents are those of an independent contractor as defined in ORS 670.600. Contractor represents and warrants that it is not and will not employ an officer, employee, or agent, of Owner, as those terms are used in ORS 30.265.

14.4. Confidentiality. The terms of the Contract Documents and all information and materials Contractor obtains from Owner Parties pertaining to the Work are confidential. Contractor shall not disclose any such information and materials without Owner's prior written consent, except when disclosure is to Persons who have a need to know such information and who first agree to maintain their confidentiality.

All information Owner obtains from Contractor concerning Contractor's costs, accounting, finances, and business operations, is confidential, and Owner shall not disclose the same without Contractor's prior written consent, except when disclosure is to Persons who have a need to know such information and who first agree to maintain their confidentiality and when required by law or court order.

This *Section* shall not apply to information that comes into the public domain unless as a result of a disclosure prohibited by this *Section*, and shall not apply to an enforceable court order. This *Section* shall survive the termination of the Agreement.

14.5. Successors and Assigns. Owner and Contractor bind themselves, their successors, and their assigns, to the other, by the terms of the Contract Documents. Contractor shall not assign or transfer

any interest in the Contract Documents, whether by merger, consolidation, dissolution, operation of law or any other manner, other than to Contractor's surety, without Owner's prior written consent.

14.6. Written Notice. Notices required under the Contract Documents shall be in writing and shall be deemed given when delivered if done so in accordance with the Contract Documents.

14.7. Governing Law; Venue. The Contract Documents shall be governed by and construed in accordance with the laws of the State of Oregon without regard to principles of conflicts of law.

14.8. Rights and Remedies. Subject to express limitations of the Contract Documents, rights and remedies available to the parties to the Agreement shall be in addition to, and not a limitation of, any available at law or in equity. No action or failure to act by Owner Parties or Contractor shall constitute a waiver of any right or duty under the Contract Documents, except as may be set forth in the Contract Documents, or as specifically agreed to in writing.

14.9. Severability. The invalidity or unenforceability of any provision of the Contract Documents shall not impair or affect the validity or enforceability of any other provision of the Contract Documents and invalid or unenforceable provisions shall be limited to the extent necessary to enable enforcement of the remainder of the Contract Documents.

14.10. Survival. All warranty and indemnification provisions of the Contract Documents, and all terms of the Contract Documents that are said to or clearly intended to, shall survive termination and completion of the Contract Documents.

Exhibit B.1

Preliminary Services Sum

See attached

Preliminary Services Sum

The Design Builder is hereby authorized to commence the Work associated with the Preliminary Services described by the Owner as program confirmation. The Preliminary Services shall include activities described in the Design Builder's Proposal, dated xxxxxxx attached hereto and incorporated herein by this reference as "Attachment 1 to Exhibit B.1. Preliminary Services described in Attachment 1 to Exhibit B.1 shall be paid for in accordance with the Agreement, subject to the not to exceed price set forth in Section 1 below.

1. The not to exceed price for the Preliminary Services shall be: $xxxxxx. This lump sum amount fee includes $xxxxxx for Design Build Services, and $xxxxxx for Reimbursable Expenses.

Exhibit B.2

Form of Early Work Amendment

See attached

EARLY WORK AMENDMENT X TO OSU DESIGN-BUILD AGREEMENT #xxxxx
PROJECT NAME:

This Early Work Amendment x ("EWA x") to the above named Agreement entered into between **Oregon State University** (**"Owner"**), and **xxxxx** (**"Design-Builder"**), individually the "Party" and collectively the "Parties", shall become effective on the date this EWA X has been signed by all the Parties (the **"EWA X Effective Date"**).

1. SECTION 6 – EARLY WORK

The "Services" shall be modified to add, delete or change the following as more specifically set out in **Attachment 1 to EWA X,** which is attached hereto and incorporated herein to this EWA X:

In accordance with Section 6.3 of the Agreement, you are hereby authorized to commence the Early Work described below and shall be paid for such Early Work in accordance with the Agreement, subject to the not to exceed price set forth below. In accordance with Section 6.3 of the Agreement, the amount paid on account of this Early Work Amendment 7 shall be included in the Pricing Amendment applicable to the Deliverable Portion of Work to which the Early Work relates.

The Early Work of this EWA X consists of the following:

A. Early Work Package including:

2. COMPENSATION
The not to exceed price for the Early Work of this EWA X shall be: **$xxxxx**

SERVICES/WORK	**COMPENSATION**
EWA X	$ xxxx
EWA X total	**$ xxxx**
Original Agreement Price – Preliminary Services Sum	$xxxxx
New Agreement Price (maximum compensation amount)	**$ xxxx**

Unless expressly modified in this EWA X or prior Amendments, all terms and conditions of the Agreement remain unchanged and in full force and effect.

In witness whereof, **Oregon State University** executes this EWA X and the Contractor does execute the same as of the EWA X Effective Date.

Design Builder

_____
Signature Date

_____
Printed Name

_____
Title

Oregon State University

_____
Bruce Daley Date

Associate Vice President University Facilities, Infrastructure and Operations

Exhibit C

Form of Pricing Amendment - GMP

See attached

Pricing Amendment

Pursuant to Section 5.11 of the Design-Build Agreement (the "Agreement") dated _____, 20___, between Owner and Design-Builder, Owner and Design-Builder agree to the following terms and conditions for the _____ Deliverable Portion of Work (this "Pricing Amendment"). Capitalized terms used but not defined in this Pricing Amendment shall have the meanings given in the Agreement.

ARTICLE 1

DEFINITIONS AND GENERAL PROVISIONS

1.1 Definitions. The following terms have the meanings set forth below:

"Affiliate" shall mean an entity in which: (i) Design-Builder has a financial interest, (ii) such entity has a financial interest in Design-Builder, (iii) Design-Builder has a direct or indirect controlling interest, or (iv) such entity has a direct or indirect controlling interest in Design-Builder.

"Back-Up Documents" shall have the meaning given in Section 2.2 of this Pricing Amendment.

"Design-Builder's Fee" shall have the meaning given in Section 2.12 of this Pricing Amendment.

"Design-Builder's Field Work" shall mean customary Work of a minor nature not feasible to Subcontract, arising from: exclusions by a Subcontractor not resolved during Subcontract buy-out, deviations in Work of Subcontractors that are not Defective Work, unaccounted-for complexity of Work coordination, and other similar reasons typical in the industry; provided, however, Design-Builder reasonably determines self-performing such Work is in Owner's best interests, obtains Owner Parties' written consent prior to executing such Work, and the cost of such Work is separately identified in Design-Builder's Applications for Payment.

"Cost of the Work" shall have the meaning given in Section 2.9 of this Pricing Amendment.

"Design Professional's Statement of Incomplete Drawings" shall mean Design Professional's detailed written description of intended, but incomplete, design and documentation that is material to the Pricing Amendment Documents for which the statement is issued.

"General Conditions Work" shall mean that portion of a Deliverable Portion of Work required to support construction operations that is not included within Design-Builder's Fee and that is set forth on attached Schedule 2.

"General Conditions Work Cost Limit" shall mean the maximum amount Owner will pay for the General Conditions Work, as set forth in the Section 2.3 below.

"GMP" shall mean guaranteed maximum price.

"GMP Total" shall mean the sum of all GMPs, as set forth in all applicable Pricing Amendments.

"Qualifications and Assumptions" shall mean, following Owner Parties' approval, Design-Builder's written statement of qualifications to, exceptions to, and assumptions in, a Pricing Amendment, all based upon the applicable Pricing Amendment Documents and the applicable Design Professional's Statement of Incomplete Drawings.

"Self-Performed Work" shall mean Work substantially performed by Design-Builder's own forces or the forces of any Affiliate.

ARTICLE 2

SUBCONTRACTING AND PAYMENTS

2.1 Access to Records. Owner shall have access to all documents and drawings Design-Builder, Subcontractors, Suppliers, and their respective contractors produce or procure for this Project, accounting records, receipts, invoices, and other documentation relating to the Project and to performance of the Work, all upon request at any time following the effective date of the Agreement and until five (5) years after Final Completion of all Work or a Deliverable Portion of Work, as the case may be.

2.2 Back-Up Documents; Audit Rights. Contractor shall cause to be kept and maintained, at a location subject to Owner's prior written approval, all records of expenditures for Project-related services rendered and Work performed, including petty cash accounts and receipted invoices. Such records shall conform to the Contract Documents' requirements and to generally accepted accounting principles (GAAP). Contractor shall furnish Owner with statements of such expenditures, with complete documentary back-up for each (the "Back-Up Documents"), with every Application for Payment, for costs of services, labor, Materials, and expenses included in the same. In addition to these monthly statements, Owner Parties shall have access to all of Contractor's Project accounting, records, and documentation pertaining to all Work (the "Audit Documents") upon request at any time from the Agreement's effective date until the expiration of a period of ten (10) years after Final Completion. Owner Parties shall have the right to produce copies of Audit Documents, at reasonable times and places, reasonably necessary for Owner Parties to audit and certify the nature and amount of the Contract Sum. Such Audit Documents subject to audit include, but are not limited to, those records pertaining to direct and indirect costs, including overhead, as they may apply to the Project. Contractor shall produce for Owner Parties those Audit Documents kept in digital form in a computer readable format in an exchange format suitable to Owner Parties.

2.2.1 Owner shall bear the costs of its audits; provided, however, if an Owner Parties' audit discloses overcharges to Owner of any kind ("Overcharges"), in excess of one-half of one percent (0.5%) of the total invoiced Contract Sum, Contractor shall pay to Owner the total amount of the Overcharges and the reasonable actual cost of the audit. If an Owners Parties' audit discloses Overcharges less than one-half of one percent (0.5%) of the total invoiced Contract Sum, Contractor shall pay to Owner only the total amount of the Overcharges. Any payments that Contractor must make due to results of an Owner Parties' audit shall be made within ninety (90) Days of Owner's presentation to Contractor of the audit. If Contractor disagrees with an Overcharges finding, Contractor shall have a Claim.

2.2.2 Notwithstanding the required retention time of Contractor's Audit Documents above, if for any reason any part of the Work or the Contract Documents is the subject of litigation, Contractor shall retain all Audit Documents until all such litigation is complete, all periods for appeal have expired, and full and final satisfaction of any judgment, order, or decree is recorded (the "Litigation Hold Period"). During the Litigation Hold Period, Owner Parties shall continue to have full access to the Audit Documents at the times and in the manners set forth above.

2.3 General Conditions Work. Design-Builder shall furnish and supervise the General Conditions Work. Design-Builder shall be responsible for, and shall pay without Owner's reimbursement, all costs and expenses, including Costs of the Work, arising from the General Conditions Work that are in excess of the General Conditions Work Cost Limit.

2.4 Subcontract Bidder Qualifications. For each bid package, Design-Builder shall submit to Owner Parties for approval, a proposed list of qualified bidders. All proposed Subcontractors shall be reputable and qualified firms, each with a sufficient record of successful performance of work similar to that Work for which they are proposed. All potential Subcontractors who by Applicable Law must be qualified and registered, shall be, and shall meet the State of Oregon Construction Contractors Board's requirements to perform work.

Owner shall have the right to approve or disapprove, in its reasonable discretion, any proposed bidder on the list submitted and shall inform Design-Builder of the same within ten (10) days after Owner Parties' receipt of the same. Design-Builder's Project bid packages shall be sent only to Owner-approved bidders. However, Owner's right to approve proposed bidders shall not be construed to relieve Design-Builder of its responsibility to propose and select qualified Subcontractors, and ensure their adequate performance of the Work, all in accordance with the Contract Documents' requirements.

2.5 Subcontractor Selection. After Design-Builder and Owner have agreed to potential bidders from the Potential Subcontractor List (the "Qualified Bidders"), Design-Builder shall solicit from such Qualified Bidders at least three (3) competitive bids for each Subcontract. If Design-Builder is unable to solicit three (3) or more competitive bids or proposals for a division of Work, Owner's prior written approval shall be required to accept any bid or proposal for that Work.

2.5.1 Unless Owner otherwise approves in writing, all Subcontract bids and proposals shall be in writing, submitted to a specific location at a specific time. Design-Builder shall time-stamp all bids and proposals when received.

2.5.2 Design-Builder shall coordinate and conduct the bid or proposal opening process. Owner Parties shall have the right, but not the obligation, to be present for all bid and proposal openings, scope review meetings, and negotiations, and shall have access to all submission materials in Design-Builder's possession.

2.5.3 Prior to award, Design-Builder shall: (i) prepare and deliver to Owner Parties a bid tabulation in a mutually agreeable form clearly comparing such bids and proposals, together with any specific back-up documentation Owner requests; (ii) review the apparent low bids and proposals and work with the firms offering the same to clarify, reduce exclusions, verify scope and quantities, and seek to minimize potential Change Orders and Claims.

2.5.4 Design-Builder shall determine the lowest bid for each solicitation that meets the requirements of this Section 2.5 and Design-Builder's reasonable performance standards; provided, however, if Design-Builder is unable to enter into a suitable Subcontract with a low bidder, Design-Builder may, with Owner's prior written approval, Subcontract with the second-lowest bidder pursuant to Section 2.5.5 below.

2.5.5 Under special circumstances and only with Owner's prior written authorization, Design-Builder may be permitted to Subcontract on a basis other than low price, including by competitive negotiation. Examples of such special circumstances include when there are single fabricators of specified Materials, special packaging requirements for Work, design-build Work, and where an alternative contracting method can be demonstrated to clearly benefit Owner and the Project. As a condition to such authorization, Owner may require that Design-Builder agree to establish and implement qualification and performance criteria for Subcontractors in these circumstances, including a scoring system within requests for proposals.

2.5.6 Owner Parties shall have the right, but not the obligation, to monitor Design-Builder's competitive Subcontract award process. Design-Builder shall cooperate in all respects with Owner Parties' monitoring. Owner Parties' monitoring shall not excuse Design-Builder from complying with the Contract Documents' requirements.

2.5.7 Notwithstanding anything to the contrary contained in this Article 2, Owner may, at its sole discretion, require Design-Builder re-solicit Subcontract bids and proposals.

2.5.8 Design-Builder shall, and require Subcontractors to, comply with all prevailing wage requirements including State of Oregon Bureau of Labor & Industries prevailing wage rates and Davis-Bacon federal wage rates provided in Exhibit R to the Agreement as and when applicable to the Work. In the event both state and federal rates apply to the same Work, the higher rate requirements shall control.

2.5.9 Design-Builder shall indemnify, defend, and hold harmless, Owner Parties, from and against any Subcontractor claim that arises due to Design-Builder's failure to incorporate the relevant terms of this Article 2 and other necessary provisions of the Contract Documents in each Subcontract.

2.5.10 Design-Builder shall not alter any material term or condition of a Subcontract without Owner's prior written consent.

2.6 Subcontractor Protests. Design-Builder shall include in its competitive Subcontracting process subject to Owner Parties' approval a protest procedure. Design-Builder shall be solely responsible for resolving Subcontract procurement protests and shall act as an independent contractor, not Owner's agent, in connection with all such procurement protests.

Design-Builder shall indemnify, defend, and hold harmless, Owner Parties, from and against all such procurement protests and resulting claims and Claims.

The provisions of this Section 2.6 solely benefit Owner and do not grant rights or remedies to any Subcontractor or other protester.

2.7 Self-Performed Work.

2.7.1 Limitation on Self-Performed Work. Neither Design-Builder nor any Affiliate shall bid on or propose any Subcontract bid package except to the extent Owner approves the same in writing, in advance. If Owner so approves, Design-Builder or its Affiliate, as the case may be, shall be subject to this Section. To qualify to Self-Perform Work, Design-Builder and its Affiliates: (i) must be performing at least fifty percent (50%) of the labor of such Work through its own respective employees; (ii) shall maintain strict separation of personnel involved with bidding and proposing the Self-Performed Work from all of Design-Builder's other personnel involved in the Project, including prohibiting communication prior to award, except for ordinary communication permitted of all bidders and proposers; (iii) shall not allocate any of the Self-Performed Work so that it is paid out of the General Conditions Work Cost Limit; and (iv) shall not use any of the Construction Contingency to pay for the Self-Performed Work.

Notwithstanding anything to the contrary, if a portion of Work that is proposed as Self-Performed Work receives fewer than two bids or proposals from responsible bidders or responsible proposers other than Design-Builder or its Affiliate, Owner may disqualify that portion of Work from Self-Performed Work eligibility and Owner may cause such Work to be solicited again.

Any rejection of a bid or proposal or required re-solicitation under this Section shall not be the basis for an increase to the GMP in any Pricing Amendment or adjustment to the Project, Design, or Construction Schedules.

2.7.2 Bidding Procedure. Design-Builder or its Affiliate, as the case may be, shall submit a sealed bid for Self-Performed Work pursuant to the procedures applicable to all Subcontractors in this Article 2; provided, however (a) Design-Builder shall nevertheless solicit Subcontractor bids for its proposed Self-Performed Work and (b) Design-Builder must publicly announce its, or its Affiliate's, intent to submit a bid for such Work when it publishes those solicitation materials. Design-Builder or its Affiliate must also submit its bid for Self-Performed Work directly to Owner Parties in a sealed envelope in advance of the deadline for Subcontractors to submit their bids for that Work.

Owner Parties shall manage the bidding process for Work that Design-Builder or its Affiliate proposes to Self-Perform, including the opening, review, and advice concerning award of, bids from potential Subcontractors. Design-Builder shall not participate in the analysis of such bids or recommend awarding the Subcontract for any Self-Performed Work. Design-Builder shall forward copies of all inquiries it receives for such Work from potential Subcontractors.

2.7.3 Self-Performed Work Fee. Design-Builder shall be entitled to Design-Builder's Fee on the Cost of the Work of approved Self-Performed Work, subject to the applicable provisions of the Contract Documents.

2.7.4 Waived Bidding. Owner may waive in writing the Self-Performed Work bidding and proposal requirements set forth in Section 2.7.1. In that event, Design-Builder or its Affiliate shall have: (i) procured all necessary Government Approvals to commence the Self-Performed Work; (ii) an Owner-approved GMP for the Self-Performed Work, including its applicable General Conditions Work costs; and (iii) an Owner-approved Construction Schedule for the Self-Performed Work. Owner shall pay for all Self-Performed Work labor at Design-Builder's or its Affiliate's cost as verified by actual labor rates, including from certified payrolls, and all Self-Performed Work equipment at pre-approved rates, all subject to the Self-Performed Work GMP.

2.8 Design-Builder's Field Work. Design-Builder or its Affiliate may self-perform Design-Builder's Field Work. Any other Work that Design-Builder or its Affiliate wishes to self-perform shall be subject to the requirements for Self-Performed Work in accordance with Section 2.7.1 above.

2.9 Cost of the Work. The "Cost of the Work" shall include only the items specifically identified below, that Design-Builder necessarily incurs in the proper performance of the Work.

2.9.1 General Conditions. Costs of all General Conditions Work, subject to the General Conditions Work Cost Limit; provided, however, the cost of General Conditions Work pertaining to any Subcontract shall not be Cost of the Work if such costs are paid pursuant to that Subcontract.

General Conditions Work costs include:

1. *Administrative Expenses*. Design-Builder's incurred costs to employ supervisory and administrative personnel when stationed at the Site, all as set forth on Exhibit __. Design-Builder's reasonable, customary, travel expenses and per diem subsistence costs incurred performing the services and the Work, not including daily travel to and from the Site; office costs incurred at the Site including telephone service, long distance telephone calls, Progress Report photography services, office equipment, office supplies; document reproduction and delivery expenses; and reasonable petty cash expenses incurred solely for the benefit of the Work.

2. *Compliance and Permitting*. Costs incurred complying with Applicable Laws, including permits, licenses, and inspections required by the Contract Documents, unless those costs arise from penalties, additional expense, or corrective actions due to acts or omissions that first failed to meet Applicable Laws.

3. *Temporary Facilities*. Costs of heat, power, lighting, and water consumed at the Site during performance of the Work, costs of temporary facilities and protection incurred during performance of the Work, and costs incurred storing Materials and equipment to be incorporated into the Project.

4. *Transportation*. Costs incurred to handle, ship, erect, and dismantle construction equipment at the Site.

2.9.2 Subcontracts. Costs incurred in connection with Work performed and Materials and equipment provided pursuant to Subcontracts; provided, however, no amount other than the express pricing of each Subcontract shall be included in the Cost of the Work and no amount of bond premiums unless Owner authorizes such costs in advance.

2.9.3 Change Order Personnel Expenses. Change order costs incurred due to the personnel who are directly engaged in the Project at the labor rates set forth in Exhibit __.

2.9.4 Equipment and Materials. Direct costs incurred, without mark-up, of Materials and equipment Design-Builder purchases directly, including their transportation and storage costs, subject to the terms of the General Conditions.

2.9.5 Rentals and Tools. Direct industry-standard costs incurred, without mark-up, of rental charges of all customary machinery, equipment, and facilities used at the Site, and their ancillary costs incurred including transportation, installation, minor repairs, replacements, dismantling and removal. Rates and quantities of such machinery, equipment, and facilities rented shall conform to industry standards, shall not exceed (a) one hundred percent (100%) of the rental rates published in the Rental Rate Blue Book for Construction Equipment, prepared by Machinery Information Division of Primedia Information Incorporated, in effect at the time of rental and (b) acquisition costs of that equipment. Notwithstanding the foregoing, Owner parties must give Design-Builder prior approval in writing for individual rental items exceeding ten thousand dollars ($10,000) (the "Rental Cost Threshold").

1. In the event Design-Builder requests to rent an item exceeding the Rental Cost Threshold, Design-Builder shall furnish Owner Parties with a reasonable rent/buy analysis, containing customary terms and rates, so that Owner may elect to cause Design-Builder to procure the item in lieu of rental, solely at Owner's option.

2. Machinery, equipment, and facilities that Design-Builder owns but rents for or to the Project, shall be rented at rates consistent with the then-current lowest prevailing market rental cost in the Project's locality.

3. In addition, rental and tool costs shall include (a) the full cost of tools incurred, without mark-up, based on purchase price for new and fair market value for previously-used, that are fully consumed in the performance of the Work and (b) the full cost of tools incurred, without mark-up, based on purchase price for new and fair market value for previously-used, less the salvage value of those tools not fully consumed; provided, however, Owner may at its option, pay the full cost of such unconsumed tools and require Design-Builder deliver to Owner the same at the end of the Project.

2.9.6 Equipment Operation, Maintenance and Repair. Ordinary costs incurred operating, maintaining, and making minor repairs to Design-Builder's owned and rented equipment. Costs incurred making major repairs or those that are abnormal shall not be Cost of the Work.

2.9.7 Emergencies. Costs incurred to prevent or combat damage, injury, or loss, due to emergencies affecting the safety of persons or property.

2.9.8 Correcting Defective Work. Subject to the terms of the Contract Documents, actual, direct costs incurred correcting Defective Work, whether damaged or otherwise, not caused by a Subcontractor, Sub-subcontractor, Supplier, or Design-Builder, and not resulting from Design-Builder's failure to meet its Contract Document requirements; provided, however, requisite or otherwise available insurance or bonds would not cover such costs.

2.9.9 Cleaning. Cost incurred removing rubbish from the Site.

2.9.10 Laboratory Fees. Laboratory fees incurred and costs of testing incurred due to the Contract Documents' requirements.

2.9.11 Royalties and License Fees. Costs incurred due to royalties and user-licenses arising from or related to the Work.

2.9.12 Taxes. Taxes, fees, and assessments Design-Builder incurs directly due to its performance of the Work, but not franchise taxes, taxes based on net income or taxes based on commercial activity; provided, however, sales tax on equipment and Materials incorporated into the

Project shall not be included so long as Owner, prior to Design-Builder's purchase of such equipment and Materials, furnishes Design-Builder with a sales tax exemption certificate.

2.9.13 Insurance. Design-Builder's insurance premiums incurred pursuant to the Contract Documents' insurance requirements, subject to the following: (a) the reimbursable cost of liability insurance shall not exceed $10 per $1,000 of the GMP Total and (b) the reimbursable cost of subcontractor default insurance, if required or permitted, shall not exceed $12 per $1,000 of the applicable Subcontracts; provided, however, in all instances, Design-Builder shall pay, without Owner's reimbursement, all deductibles, self-insured retentions, and co-payments.

2.9.14 Bonds. Design-Builder's bond premiums incurred pursuant to the Contract Documents' requirements. Design-Builder shall require each Subcontractor to separately identify its bond costs and Design-Builder shall document those costs separately for Owner Parties' review.

2.9.15 Casualties. Costs and losses reasonably incurred in connection with any casualty or peril arising from or relating to the Project not caused by a Subcontractor, Sub-subcontractor, Supplier, or Design-Builder, and not resulting from Design-Builder's failure to meet its Contract Document requirements; provided, however, requisite or otherwise available insurance or bonds would not cover such costs.

2.9.16 Miscellaneous Cost Items. Miscellaneous expenditures not otherwise identified above as Cost of the Work and incurred due to Work performed; provided, however, Owner has approved each such expenditure prior to it being incurred.

2.9.17 Self-Performed Work. Incurred costs of Design-Builder's Field Work and incurred costs of Design-Builder's Self-Performed Work for those bids and proposals accepted by Owner in writing, subject to the provisions of Section 2.7.1 above.

2.10 Not Cost of the Work. The following costs are not Cost of the Work:

2.10.1 General Conditions. General Conditions Work costs not payable as Cost of the Work including:

1. *Costs in Excess of General Conditions Work Cost Limit*. Costs arising from or related to the General Conditions Work in excess of the General Conditions Work Cost Limit.

2. *Administrative Expenses*. Design-Builder's personnel and office costs other than those set forth above.

3. *Overhead and General Expenses*. Design-Builder's overhead costs and general expenses of doing business, except as expressly set forth above.

4. *Special Compensation*. Merit, incentive, and bonus payments, except as set forth above.

2.10.2 Costs in Excess of GMP. All costs in excess of the GMP (as the same may be increased or decreased by Change Order from time to time) applicable to such costs.

2.10.3 Design-Builder's Capital: Design-Builder's capital expenses arising from or related to the Project.

2.10.4 Negligence; Infidelity; Dishonesty: Losses, costs, and expenses due to (a) fault or negligence or (b) infidelity or dishonesty of Design-Builder, Subcontractors, Sub-subcontractors, Suppliers, or anyone directly or indirectly employed by any of them.

2.11 Other Limitations on Cost of the Work.

2.11.1 No Duplication. Notwithstanding the definition and categorization of Cost of the Work contained in this Article 2 or elsewhere in the Contract Documents, there shall be no duplication of

payment in the event a particular item can be categorized as more than one of the types of reimbursable Cost of the Work.

2.11.2 Overtime. Unless it is expressly set forth in a Pricing Amendment, prior to Design-Builder's or Subcontractors' or Sub-subcontractors' or Suppliers' use of personnel in overtime to perform Work, Design-Builder shall give Owner notice and opportunity to comment and such overtime Work shall be implemented in a cost efficient manner. In no event shall costs of overtime exceed any GMP without approved Change Order to the applicable Pricing Amendment.

2.11.3 Recoveries. If Design-Builder recovers from a source other than Owner, whether by payment, labor, materials, or otherwise, for Work that Owner has paid (e.g., a Subcontractor, an insurer, or a surety), Design-Builder shall credit Owner the value of such recovery.

2.11.4 Discounts. Design-Builder agrees to use best efforts to secure all discounts and rebates available to the Work. Cost of the Work shall be reduced by all such discounts and rebates, which shall accrue exclusively to Owner; provided, however, Owner makes payment when needed to obtain such discounts and rebates.

2.11.5 Spare Materials. As set forth in Section 4.13.5 of the General Conditions, the fair market value of Spare Materials and excess equipment shall accrue to Owner.

ARTICLE 3

PRICING

3.1 **Contract Sum**. Subject to the terms of the Contract Documents, Owner shall pay Design-Builder the Contract Sum, which shall equal the sum of the Cost of the Work, the General Conditions Lump Sum and the Design-Builder's Fee, but which shall not exceed the GMP Total. In addition, Owner's payments to Design-Builder for a Deliverable Portion of Work shall not exceed the GMP for that Deliverable Portion of Work, as set forth below.

3.2 **GMP 1**. Design-Builder's GMP for the Deliverable Portion of Work is _____. This is inclusive of the Preliminary Services Sum, Cost of Work, General Conditions Work Lump Sum, Construction Contingency and the Design-Builder's Fee.

3.3 **General Conditions Lump Sum**. The General Conditions Lump Sum (which is included in the above GMP amount) for the Deliverable Portion of Work is _____.

3.4 **Guaranteed Substantial Completion Date.** The Guaranteed Substantial Completion Date for the Deliverable Portion of Work is _____.

3.5 **Guaranteed Final Completion Date.** The Guaranteed Final Completion Date for the Deliverable Portion of Work is _____.

3.6 **Design-Builder's Fee**. Subject to the GMP Total, "Design-Builder's Fee" for the Work under this Agreement shall be a lump sum amount of _____.

3.7 **Construction Contingency**. Subject to Section 7.4 of the Agreement, the Construction Contingency under this GMP is _____.

ARTICLE 4

CLARIFICATIONS, ASSUMPTIONS AND EXCLUSIONS; CONSTRUCTION DOCUMENTS

4.1 **Clarifications, Assumptions and Exclusions.** Following are the Design-Builder's clarifications, assumptions and exclusions.

4.2 **Construction Documents**. The Construction Documents applicable to this GMP are as follows:

4.3 **Exhibits.** The following exhibits are attached to this GMP and incorporated herein by this reference.

4.3.1 Exhibit A – Schedule of Values

4.3.2 Exhibit B – Schedule

4.3.3 Exhibit C – General Conditions Costs Breakout

4.4 **Agreement; Conflicts**. Except as set forth in this GMP, the Agreement shall remain in full force and effect. In the event of an irreconcilable conflict between the terms of the Agreement and those of this GMP, the terms of this GMP, control.

4.5 **No Claims Representation**. As of the GMP Effective Date, Design-Builder acknowledges it is neither aware of, nor has reserved, any Claim.

4.6 **Effective Date**. This GMP shall take effect upon the date it is last signed ("GMP Effective Date") and may be signed in separate counterparts, each of which when signed and delivered shall be an original, and all which when taken together, shall constitute one instrument.

4.7 **GMP Summary.**

SERVICES/WORK	**COMPENSATION**
GMP	$XXXXX
GMP Total	**$XXXXXX**
Original Agreement Price – Preliminary Services Sum Early Work Amendment 1, if applicable	$XXXXXX
Agreement Guaranteed Maximum Price (maximum compensation amount)	**$XXXXXX**

In witness whereof, **Oregon State University** executes this GMP and the Design-Builder does execute the same as of the GMP 1 Effective Date.

DESIGN-BUILDER

_____

Signature Date

_____

Printed Name

_____

Title

Oregon State University

_____

Paul J. Odenthal, PE, CEM Date

Senior Associate Vice President for Administration

Exhibit D

Project Criteria

See attached

[Insert Project Criteria]

Exhibit E

Key Personnel and Hourly Rates

See attached

Design-Builder's Key Personnel

The personnel indicated below shall be committed to the Project and shall not be assigned any other work responsibilities that lessen or hinder their ability to perform their Project responsibilities:

1. Project Executive. Design-Builder shall assign _____ as Project Executive to supervise Design-Builder's services and the Work and be available to Owner at all reasonable times.

2. Senior Project Manager. Design-Builder shall assign _____ as Senior Project Manager to supervise the Work and be available to Owner at all reasonable times.

3. Project Manager. Design-Builder shall assign _____ as Project Manager to supervise the Work and be available to Owner at all reasonable times.

4. General Superintendent. Design-Builder shall assign _____ as General Superintendent to supervise the Work.

5. Design Manager. Design-Builder shall assign _____ as Design Manager to supervise Design-Builder's Design Services.

6. Submittals Coordinator. Design-Builder shall assign _____ as Design-Builder's Submittals Coordinator to coordinate all Submittals and shall check for conflicts, completeness, and accuracy, and confirm such Submittals conform to the requirements of the Contract Documents and are appropriate for Owner Parties' review.

7. Other Personnel. Design-Builder shall assign other persons as necessary who shall be responsible for the job descriptions set forth next to each of their names. [Note: Design-Builder to provide for Owner's approval.]

Design-Builder's Personnel Rates

[Note: Design-Builder to provide hourly rates for Owner's approval]

Exhibit F

Form of Payment Claim Waiver

See attached

[Note: Insert OSU's preferred form of claim waiver, if any.]

Exhibit G

Per Diem Liquidated Damages

See attached

Per Diem Liquidated Damages

Deliverable Portion of the Work 1 [_____]	Guaranteed Substantial Completion Date [_____]	Per Diem Damages (30 Days) [_____]	Per Diem Damages (60 Days) [_____]	Per Diem Damages (90 Days) [_____]
Deliverable Portion of the Work 2 [_____]	Guaranteed Substantial Completion Date [_____]	Per Diem Damages (30 Days) [_____]	Per Diem Damages (60 Days) [_____]	Per Diem Damages (90 Days) [_____]
Deliverable Portion of the Work 3 [_____]	Guaranteed Substantial Completion Date [_____]	Per Diem Damages (30 Days) [_____]	Per Diem Damages (60 Days) [_____]	Per Diem Damages (90 Days) [_____]
Deliverable Portion of the Work 4 [_____]	Guaranteed Substantial Completion Date [_____]	Per Diem Damages (30 Days) [_____]	Per Diem Damages (60 Days) [_____]	Per Diem Damages (90 Days) [_____]

Exhibit H

Notice and Contact Information

Notices required under the terms of the Agreement shall be given to the attention of each party's representative designated below using the following contact information.

Owner:

Attn:

Phone:

Fax:

Email:

with copy to:

Attn:

Phone:

Fax:

Email:

Owner Parties:

Attn:

Phone:

Fax:

Email:

with copy to:

Attn:

Phone: _____

Fax: _____

Email: _____

Design-Builder: _____

_____

_____

Attn: _____

Phone: _____

Fax: _____

Email: _____

***with copy to*:** _____

_____

_____

Attn: _____

Phone: _____

Fax: _____

Email: _____

Design Professional: _____

_____

_____

Attn: _____

Phone: _____

Fax: _____

Email: _____

***with copy to*:** _____

_____

_____

Attn: _____

Phone: _____

Fax: _____

Email: _____

Exhibit I

Owner's Standard Requirements

See attached

Security/Background Checks:

The OSU facilities in which work performed under this Agreement is performed are designated as critical, occupied or security-sensitive facilities. Thus, Contractor shall conduct criminal background checks, including sex offender registration checks, (for both: Oregon at a minimum, and national for Contractor employees that formerly lived outside of the state of Oregon) on each Contractor employee and agent with satisfactory results before referral or placement at any OSU work location. The Contractor shall also conduct drug and alcohol testing of each Contractor employee and agent with satisfactory results before referral or placement at any OSU work location. Contractor must perform the criminal background checks and drug and alcohol testing within the 12 months immediately preceding referral or placement at any OSU work location.

Disqualifying crimes may include: 1) felony convictions of any kind within the last 8 years, 2) all crimes involving weapons of any kind ever committed, 3) all person to person crimes involving physical injury to another person ever committed, 4) sexual offenses, including stalking, and 5) child abuse, molestation, child pornography or other crimes involving child endangerment, including neglect and abandonment ever committed.

Contractor shall require Contractor's employees and agents to self-disclose to Contractor any new convictions that occur within three business days of the conviction and Contractor shall reassess the individual's assignment under this Contract.

OSU, at its discretion, may require Contractor to reassign a Contractor employee or agent to no longer perform work under this Agreement or for OSU if, at any time, OSU believes that the Contractor employee or agent may create a danger to the health or safety of the campus community.

Contractor is solely responsible for complying with all applicable federal, state or local laws, rule, and regulations, including but not limited to the Fair Credit Reporting Act and equal opportunity laws and regulations, when conducting background checks. The costs and Fair Credit Reporting Act obligations for criminal background checks and drug and alcohol testing are the responsibility of Contractor.

Contractor shall require Contractor's subcontractors and agents providing services under this Agreement to comply with this provision. OSU may audit Contractor's background check and drug and alcohol testing processes at any time to ensure compliance with this section. Failure of Contractor to comply with this section is a material breach of the Agreement and may result in OSU seeking monetary damages or pursue other remedies, termination by OSU without further liability or obligation, or both. Contractor shall indemnify, defend, and hold harmless OSU and its directors, agents, trustees, and employees from all claims, suits, and actions arising out of or related to any and all claims relating to the conducting of such checks and testing and any adverse action that may be taken as a result of such checks and testing.

OSU to add/supplement as needed

Exhibit J

Project Description

See attached

[Insert written description of the Project]

Exhibit K

Quality Management and Control Plan

See attached

- Cost control system
- Breakdown of quality control responsibilities to the various Project participants
- Quality Control matrix identifying and cross referencing
    - Testing
    - Inspections
    - Submittals
    - Project participants
- Inspection and testing plans for all critical Work including commissioning
- Field monitoring and inspection report qualitative examples issuance schedule
- Contractor's Subcontractor's quality control audit plan
- Defective Work identification, reporting, and correction procedures

[Design-Builder to insert written descriptions and supplement the above list]

Exhibit L

Site Description

See attached

[Insert description of the Site, which may include a legal description and survey]

Exhibit M

Fee Matrix

See attached

Cost Matrix

Project Name: SARL CO6 Modernization Design Build

Oregon State University

DB Fee	_____%	
DB Preliminary Services Sum	$	Lump Sum
DB General Conditions Monthly Charge	$	Per Month
DB General Conditions Duration		# of Months

Cost Responsibility Matrix forDB

		DB Fee	Precon Fee	General Conditions	Direct Cost of Work	Owner
	Construction Staff (For Project Specific Time)					
	In response to the evaluative sections of the solicitation, hourly rates for the staff listed below must be attributable to actual costs - base hourly wage paid to employee including fringe benefits, vacation, health care, insurance and payroll taxes only. DOES NOT include standard compensation bonus.					
1	CM/GC or DB Project Manager and all on-site CM/GC or DB personnel based upon OSU approved CM/GC organization chart and percentage of time that each person is dedicated to the Project. On-Site personnel may include construction project manager, superintendents, project/field engineers, coordinator, scheduler, cost estimator, safety, quality control, administrator, Project accountant, and other Project specific personnel deemed necessary for the Project and accounting/administration.			X		
2	Costs related to transportation (including trucks, shuttles, parking, corporate vehicles and their operation and maintenance, owned or rented) for all staffing in Item 1.	X				
	Communication devices, computer, tablet, project specific software, vehicle, gas, prof. development. Commuting to and from Project site and any other misc. cost associated with labor.	X				
3	Standard Compensation Bonuses	X				
4	CM/GC home (or main), branch and/or regional office general, administrative and support staff who provide corporate management oversight, corporate accounting, corporate safety, corporate quality control, corporate administration, corporate IT, legal services, corporate payroll and benefits	X				
5	CM/GC Profit on all Work	X				
	Temporary Facilities					
6	Office/Trailer Rental, Furnishings, and Cleaning			X		
7	Copy/Fax/Printer & Supplies			X		
8	PPE Safety Equipment, Fire Ext & First Aid			X		
9	Fire Watch				X	
10	Temporary Toilets			X		
11	Water/Ice/Cups			X		
12	Temporary Stairs/Scaffolding				X	
13	Temporary Enclosures/Weather Protection				X	
14	Temporary Building Heating			X		
15	Project Signs & Bulletin Boards			X		
16	Temporary Fencing			X		
17	Covered Walkways			X		
18	Barricades				X	
	Overhead, Fee, Insurance and Bonds					
19	Profit and Overhead	X				

		DB Fee	Precon Fee	General Conditions	Direct Cost of Work	Owner
20	Builder's Risk Insurance				X - No Mark up	
21	General Liability	X				
22	Excess Liability Coverage	X				
23	Performance & Payment Bonds				X - No Mark up	
24	Subcontractor Bonds/Subcontractor Default Insurance				X - No Mark up	
	On-Site Equipment and Utilities					
25	Job Site Utility Set up			X		
26	Job Site Utility Consumption					X
27	Document Management Programs			X		
28	Safety/Ceremony Lunches	X				
29	Construction Progress Photos			X		
30	Off-Site Storage			X		
31	Housekeeping & Final Clean			X		
32	Trash & Recycling			X		
33	Dust Controls/Street Cleaning				X	
34	Snow and Ice Removal				X	
35	Dewatering Equipment				X	
36	Temporary Roads (if required)				X	
37	Radio equipment			X		
38	On Site Storage			X		
39	Lifts (Rented or Contractor owned)			X		
40	Lift Operators			X		
41	Fuel, Repairs, Maintenance for Lifts			X		
42	Small Tools Purchase	X				
43	Small Equipment Rental			X		
44	Crane and Hoisting				X	
45	Temporary Elevator Rental				X	
46	Elevator Operator				X	
	Reproduction and Printing					
47	Reproduction and Printing during construction			X		
	Permits and Special Fees					
48	Craft Parking when parking lot is not already provided by Owner			X - No Mark up		
49	PIPC Permit					X
50	General Building Permit					X
51	Craft Permits			X - No Mark up		
52	Surveying				X	

Exhibit N

Insurance Requirements

See attached

INSURANCE REQUIREMENTS

A. GENERAL.

Design Builder shall, and shall cause each Subcontractor to, maintain the insurance coverages set forth below:

1. **Commercial General Liability (CGL)**

   $2,000,000 Each Occurrence

   $4,000,000 General Aggregate – Per Project Aggregate

   $4,000,000 Products/Completed Operations Aggregate

   $2,000,000 Personal Injury

2. **Business Automobile**

   $1,000,000 Combined Single Limit

3. **Workers' Compensation/Employers' Liability (Stop Gap)**

   Statutory Workers' Compensation – Coverage A

   $1,000,000 Each Accident

   $1,000,000 Disease – Policy Limits

   $1,000,000 Disease – Each Employee

4. **Contractors Pollution Liability**

   $3,000,000 Each Occurrence and General Aggregate

5. **Excess Umbrella Liability:**

   For Contractor:

   $5,000,000 Each Occurrence/Annual General Aggregate

   For Subcontractors, unless a higher limit is set by Subcontract:

   Where the Subcontract Sum is $500,000 or less, $2,000,000 Each Occurrence/Annual General Aggregate

   Where the Subcontract Sum is over $500,000 but not more than $2,000,000, $5,000,000 Each Occurrence/Annual General Aggregate

   Where the Subcontract Sum is over $2,000,000, $10,000,000 Each Occurrence/Annual General Aggregate

B. ADDITIONAL REQUIREMENTS.

1. **Commercial General and Excess Umbrella Liability Insurance.**

   a) CGL insurance shall be written on current ISO occurrence for CG 00 01 or its equivalent if Owner approves and shall cover liability arising from premises, operations, independent contractors, products-completed operations, death, bodily injury, property damage, personal injury and advertising injury and liability assumed under an insured contract. Excess Umbrella Insurance coverage shall be provided on a follow-form basis and Design Builder shall be responsible for any gaps between

underlying coverage and excess coverage for all policies required under the terms of this Agreement.

b) The Indemnitees shall be included as additional insureds under the CGL, excess umbrella liability and contractors pollution liability coverages. The additional insured coverage under the CGL shall be on current ISO additional insured endorsements CG 20 10 (07 04) and CG 20 37 (07 04) or substitutes providing equivalent coverage if Owner approves. Such insurance shall apply as primary insurance to the additional insureds.

2. **Completed Operations Liability Insurance.**

   Completed operations coverage required by the Contract Documents shall be maintained for at least ten (10) years following Final Completion of the Work.

3. **Business Auto and Umbrella Liability Insurance.**

   a) Business Auto and Umbrella Liability Insurance shall cover liability arising out of any auto including owned, unowned, and hired.

   b) Business auto coverage shall be written on current ISO form CA 00 01, CA 00 05, CA 00 12, CA 00 20 or its equivalent if Owner approves.

4. **Railroad Protective Liability.**

   a) Where required by the railroad for construction or demolition activities, Subcontractors shall procure and maintain Railroad Protective Liability meeting the railroad's requirements.

   b) If the Work involves construction or demolition operations at or near railroad property the Subcontractors' CGL policies shall contain current ISO Form Endorsement CG 24 17 01 96 or substitute form providing equivalent coverage.

5. **General/Certificates of Insurance.**

   a) All insurance policies shall: (i) be written by insurance companies authorized to do business in the State of Oregon having a financial size of VII or higher and a rating of not less than "A-X" in the latest version of Best's Insurance Guide and (ii) not be suspended, canceled, or altered except after thirty (30) days' prior written notice to Owner by certified mail, return receipt requested.

   b) Prior to commencement of any applicable Work, Design Builder shall file with Owner certificates of insurance evidencing the required insurance is in effect. At Owner's request, Design Builder shall deliver to Owner the actual insurance policies and any endorsements or riders. The endorsements and riders shall include cross-claim and severability of interests endorsements.

6. **Deductibles.**

   a) CGL and Workers' Compensation/Employer's Liability (Stop Gap) policies shall not include a deductible or self-insured retention of more than $200,000 per claim.

7. **Professional Liability Insurance.**

   a) Design Builder shall maintain professional liability insurance for claims arising from any professional services Design Builder and its Subcontractors perform on the Project. The professional liability insurance shall be maintained throughout the

Project and for a period of not less than eight (8) years after Final Completion of the Work. Contractor's consultants and contractors working on Contractor's behalf shall maintain professional liability insurance with limits customary for the scope and character of the professional services performed.

b) Minimum Limits:
    a. $2,000,000 Each Occurrence
    b. $4,000,000 General Aggregate – Per Project Aggregate

C. <u>BUILDERS' RISK INSURANCE</u>.

1. Design Builder shall place and maintain, on an "all-risk" or "special form" policy form, builders risk insurance for the Project, insuring against the perils and including extended coverage and coverage for physical loss or damage. Design Builder shall be responsible for $50,000 per claim deductible under the builders risk policy if the loss is caused by Contractor, its Subcontractor, Sub-subcontractor or other person or entity for whose acts Design Builder may be liable. Owner and Design Builder shall cooperate with each other and jointly adjust and settle any loss insured under the builders risk policy. Any loss shall be made payable to Design Builder as fiduciary for the insureds, as their interests may appear, and Design Builder shall pay to Owner its just share of insurance proceeds. Design Builder shall pay its Subcontractors and sub-subcontractors their just share of insurance proceeds received, and by appropriate agreements shall require all Subcontractors and Sub-Subcontractors to make their respective obligated payments.
2. Owner and Design Builder waive all rights against (a) each other and their respective contractors, subcontractors, sub-subcontractors, agents and employees, and (b) Design Professional and any of its respective consultants, contractors, agents and employees, for damages caused by perils to the extent covered by the builders risk policy, except such rights as any of them may have to the proceeds of such insurance. The builders risk policy shall expressly provide such waivers of subrogation which shall be effective against all parties whether they have a duty of indemnification, pay the insurance premium directly or indirectly, or have an insurable interest in the damaged property.
3. The builders risk insurance shall include Owner and Design Builder as named insureds. Subcontractors and Sub-subcontractors shall be loss payees as their interests may appear.

D. <u>SUBCONTRACTOR DEFAULT INSURANCE</u>.

1. Subject to the terms of the Agreement, and if permitted by the Agreement, including but not limited to Section 8.3.2 of the General Conditions, Design Builder may place and maintain subcontractor default insurance.
2. The premium cost of any subcontractor default insurance policy permitted and chargeable to Owner as a cost of the Work shall be limited in accordance with the terms of the Pricing Amendment.

Exhibit O

Form of Bonds

See attached

[OREGON STATE UNIVERSITY]

STANDARD FORM OF

PERFORMANCE BOND

Bond No._____
Contract_____
Contract Date_____
Project Name_____

_____(Surety #1)
_____(Surety #2)*
* *If using multiple sureties*

Bond Amount No. 1: $_____
Bond Amount No. 2:* $_____
Total Penal Sum of Bond: $_____

We, _____, as Principal, and the above identified Surety or Sureties, collectively as Surety, authorized to transact surety business in Oregon, hereby jointly and severally bind ourselves, our respective heirs, executors, administrators, successors and assigns firmly by these presents and will pay unto [Oregon State University], as Obligee, the sum of (Total Penal Sum of Bond) _____, lawful money of the United States of America (provided, that we the Surety bind ourselves, and our heirs, executors, administrators, successors and assigns, in such sum "jointly and severally" as well as "severally" only for the purpose of allowing a joint action or actions against any or all of us, and for all other purposes each Surety binds itself, jointly and severally with the Principal, for the payment of such sum only as is set forth opposite the name of such Surety), and

WHEREAS, the Principal has entered into the above-referenced written Contract with the Obligee;

WHEREAS, the terms and conditions of the Contract are made a part of this Performance Bond by reference, whether or not attached to the Contract; and

WHEREAS, the Principal has agreed to perform the Contract in accordance with its terms, conditions, requirements, plans and specifications, and all authorized modifications of the Contract which change the amount of the work, the amount of the Contract, or constitute an authorized extension of the time for performance;

NOW, THEREFORE, THE CONDITION OF THIS BOND IS SUCH that if the Principal herein shall faithfully and truly observe and comply with the terms, conditions and provisions of the Contract, in all respects, and shall well and truly and fully do and perform all matters and things undertaken by Contractor to be performed under the Contract, upon the terms set forth therein, and within the time prescribed therein, or as extended as provided in the Contract, with or without notice to the Surety, and shall indemnify and save harmless Obligee and the_____ (name of any other Owner agency), and members thereof, their respective officers, employees and agents, from and against any direct or indirect damages of every kind and description, and claims of every kind and description, that shall be suffered or claimed to be suffered in connection with or arising out of performance of the Contract by the Principal or its subcontractors, and shall in all respects perform said Contract according to law, then this obligation is to be void; otherwise, it shall remain in full force and effect.

Surety hereby waives notice of all modifications and amendments to the Contract and agrees that the obligations undertaken by this Performance Bond shall not be impaired in any manner by reason of the same.

Surety hereby agrees this Performance Bond shall be deemed amended automatically and immediately, without formal or separate amendments hereto or notice to the Surety thereof, upon any amendment to the Contract, so as to bind the Principal and Surety, jointly and severally, to the full and faithful performance of the Contract as so amended or modified, provided only that the Surety shall not be liable for more than the Total Penal Sum of Bond.

Nonpayment of the bond premium will not invalidate this bond nor shall Obligee, [or the above-referenced agency(ies)], be obligated for the payment of any premiums.

This bond is given and received under authority of ORS Chapter 279C, the provisions of which are incorporated into this bond and made a part hereof.

No right of action shall accrue on this Performance Bond to any person or entity other than Obligee and its executors, administrators, successors and assigns.

IN WITNESS WHEREOF, WE HAVE CAUSED THIS INSTRUMENT TO BE SIGNED AND SEALED BY OUR DULY AUTHORIZED LEGAL REPRESENTATIVES.

[*Signature page follows*]

Dated this _____ day of _____, 20__.

PRINCIPAL: _____

By_____
Signature

_____
Official Capacity

Attest: _____
Corporation Secretary

SURETY: _____
[Add signatures for each surety if using multiple bonds]

BY ATTORNEY-IN-FACT:
[Power-of-Attorney must accompany each surety bond]

_____
Name

_____
Signature

_____
Address

_____
City State Zip

_____ _____
Phone Fax

[OREGON STATE UNIVERSITY]

STANDARD FORM OF

PAYMENT BOND

Bond No._____
Contract_____
Contract Date_____
Project Name_____

_____(Surety #1)	Bond Amount No. 1:	$ _____
_____(Surety #2)*	Bond Amount No. 2:*	$ _____
* *If using multiple sureties*	Total Penal Sum of Bond:	$ _____

We, _____, as Principal, and the above identified Surety or Sureties, collectively as Surety, authorized to transact surety business in Oregon, hereby jointly and severally bind ourselves, our respective heirs, executors, administrators, successors and assigns firmly by these presents and will pay unto [Oregon State University], as Obligee, the sum of (Total Penal Sum of Bond) _____ lawful money of the United States of America (provided, that we the Surety bind ourselves, and our heirs, executors, administrators, successors and assigns, in such sum "jointly and severally" as well as "severally" only for the purpose of allowing a joint action or actions against any or all of us, and for all other purposes each Surety binds itself, jointly and severally with the Principal, for the payment of such sum only as is set forth opposite the name of such Surety), and

WHEREAS, Principal has entered into the above-referenced written Contract with the Obligee;

WHEREAS, the terms and conditions of the Contract are made a part of this Payment Bond by reference, whether or not attached to the Contract; and

WHEREAS, the Principal has agreed to perform the Contract in accordance with its terms, conditions, requirements, plans and specifications, and all authorized modifications of the Contract which change the amount of the work, the amount of the Contract, or constitute an authorized extension of the time for performance;

NOW, THEREFORE, THE CONDITION OF THIS BOND IS SUCH that if the Principal shall faithfully and truly observe and comply with the terms, conditions and provisions of the Contract, in all respects, and shall well and truly and fully do and perform all matters and things by it undertaken to be performed under said Contract and any duly authorized modifications that are made, upon the terms set forth therein, and within the time prescribed therein, or as extended therein as provided in the Contract, with or without notice to the Sureties, and shall indemnify and save harmless Obligee and the _____ (name of any other Owner agency), and members thereof, their respective officers, employees and agents, against any claim for direct or indirect damages of every kind and description that shall be suffered or claimed to be suffered in connection with or arising out of the performance of the Contract by the Principal or its subcontractors, and shall promptly pay all persons supplying labor, materials, or services to the Principal or its subcontractors for prosecution of the work provided in the Contract; and shall promptly pay all contributions due the State Industrial Accident Fund and the State Unemployment Compensation Fund from the Principal or its subcontractors in connection with the performance of the Contract; and shall pay over to the Oregon Department of Revenue all sums required to be deducted and retained from the wages of employees of the Principal and its subcontractors

pursuant to ORS 316.167, and shall permit no lien nor claim to be filed or prosecuted against the Obligee, the State, Project or the work of the Contract, on account of any labor, materials, or services; and shall do all things required of the Principal by the laws of this State, then this obligation shall be void; otherwise, it shall remain in full force and effect.

Surety hereby waives notice of all modifications and amendments to the Contract and agrees that the obligations undertaken by this Payment Bond shall not be impaired in any manner by reason of the same.

Surety hereby agrees this Payment Bond shall be deemed amended automatically and immediately, without formal or separate amendments hereto or notice to the Surety thereof, upon any amendment to the Contract, so as to bind the Principal and Surety, jointly and severally, to the full and faithful performance of the Contract as so amended or modified, provided only that the Surety shall not be liable for more than the Total Penal Sum of Bond.

Nonpayment of the bond premium will not invalidate this bond nor shall the Obligee, [or the above-referenced agency(ies)], be obligated for the payment of any premiums.

This bond is given and received under authority of ORS Chapter 279C, the provisions of which hereby are incorporated into this bond and made a part hereof.

This Payment Bond is made for the use and benefit of all persons and entities who may furnish materials or perform labor or services on account of the construction to be performed or supplied in accordance with the Contract, and each of them may sue hereon.

IN WITNESS WHEREOF, WE HAVE CAUSED THIS INSTRUMENT TO BE EXECUTED AND SEALED BY OUR DULY AUTHORIZED LEGAL REPRESENTATIVES:

[*Signature page follows*]

Dated this _____ day of _____, 20__.

PRINCIPAL: _____

By_____
Signature

_____
Official Capacity

Attest: _____
Corporation Secretary

SURETY: _____
[Add signatures for each surety if using multiple bonds]

BY ATTORNEY-IN-FACT:
[Power-of-Attorney must accompany each surety bond]

_____
Name

_____
Signature

_____
Address

_____
City State Zip

_____
Phone Fax

Exhibit P

Form of Change Order

See attached

CHANGE ORDER ONE TO OSU DESIGN BUILDER AGREEMENT #XXXX
PROJECT NAME: XXX

This Change Order One ("**CO**") to the above named Agreement entered into between **Oregon State University** (**"Owner"**), and **Contractor Name** (**"Contractor"**), individually the "Party" and collectively the "Parties", shall become effective on the date this CO has been signed by all the Parties (the **"CO Effective Date").**

1. SCOPE OF WORK AND COMPENSATION

The "Work" shall be modified to add, delete or change the following as more specifically set out in **Exhibit A, Scope of Work**, which is attached hereto and incorporated herein to this CO:

SCOPE OF WORK	**COMPENSATION**	
	$ 0.00	Fixed Fee
	$ 0.00	Fixed Fee
	$ 0.00	Time & Materials
Change Order total	**$ 0.00**	
Original Agreement Price	$ 0.00	
Previous executed Change Orders	$ 0.00	
New Agreement Price (maximum compensation amount)	**$ 0.00**	

2. AGREEMENT TERM

The Final Completion date shall be changed from September 30, 2019 to **December 31, 2019** due to (reason). No work shall take place after this date.

Unless expressly modified in this CO or prior CO's, all terms and conditions of the Agreement remain unchanged and in full force and effect.

In witness whereof, **Oregon State University** executes this CO and the Contractor does execute the same as of the Effective Date.

Contractor Name

_____
Signature Date

_____
Printed Name

_____
Title

Oregon State University

_____
Bruce Daley Date
Associate Vice President
University Facilities, Infrastructure and Operations

Exhibit Q

Change Pricing

1. Unless Owner otherwise previously approves in writing, an increase or decrease in the GMP by Change Order shall be determined by one of the following (at Owner's sole discretion):

    a. Stipulated lump sum acceptable to Owner and Design Builder, based on Design Builder's estimated costs, with allowance for Design Builder's profit and overhead, as set forth in Section 2 below. Design Builder shall provide to Owner Parties supporting documentation of the increase or decrease in the GMP sufficient, in Owner Parties reasonable opinion, to evaluate Design Builder's estimated costs.

    b. Unit Prices stated in the Contract Documents, including but not limited those identified in attached **Schedule 1**, or to which Owner and Design Builder subsequently agree. Design Builder shall submit to Owner Parties an itemized list of quantities and applicable unit price for each, in form and to the level of detail Owner Parties reasonably require.

    c. Actual Cost of the Work of the change, plus allowances for overhead and profit, all as set forth below and not to exceed a pre-determined maximum amount**.** Design Builder shall provide to Owner Parties supporting documentation of the actual Cost of the Work of the change sufficient, in Owner Parties reasonable opinion, to support Design Builder's costs.

2. The allowable overhead and profit mark-up included in each Change Order or Amendment (as applicable) shall be as follows; provided, however, if Unit Prices are used to determine Change Order pricing for all or a portion of the applicable Work, Design Builder shall be entitled to only those Unit Prices and no additional mark-up for that Work:

	Overhead/ Profit
Design Builder:	**15%** on allowable Labor costs **10%** on allowable materials and equipment costs **7.5%** on allowable Sub-Subcontractor costs
Architect during Design Phase:	**10%** on subconsultants No Overhead and Profit on Architect's own scope of work

Subcontractors during Construction Phase:	**15%** on allowable Labor costs **10%** on allowable materials and equipment costs **7.5%** on allowable Sub-Subcontractor costs
Architect during Construction Phase:	Same as Design Phase

3. The percentages allowed for overhead and profit under Section 2 above pertaining to Subcontractors include all costs resulting from each Change Order, even if not expressly set forth as a cost in section 4 below.

4. The term “costs” in this Exhibit Q means: (a) actual, direct costs of labor, including social security, customary fringe benefits, and workers' compensation insurance; (b) actual, direct costs of Materials; (c) out of pocket rental costs of machinery and equipment at rates prevailing in the area where the Project is located; (d) out of pocket costs of premiums for all bonds and insurance, permit fees, and taxes related directly to the Work; and (e) actual, direct costs of Key Personnel directly attributable to the Change Order if the Substantial Completion date of the applicable Deliverable Portion of Work is changed.

5. Upon Owner's request, Design Builder or Subcontractor shall submit evidence to substantiate all costs. Materials shall be quoted at prices including all discounts realized.

6. When additions and credits apply to a Change Order both increasing and decreasing the GMP, the allowable overhead and profit, if applicable in accordance with Section 2 above, shall be determined based on a net increase or decrease to the GMP.

Schedule 1

Unit Prices

In addition to those Unit Prices set forth in the Pricing Amendment dated _____, which are incorporated in this Schedule 1 by this reference, the following Unit Prices shall be used when determining this Change Order pricing:

Exhibit R

Prevailing Wage Rates

1. **State of Oregon Bureau of Labor and Industries Prevailing Wage Rates.** As provided in the Agreement, this Project is subject to payment of prevailing wages under ORS 279C.800 to 279C.870. Each worker the Design-Builder, subcontractor or other person who is party to the agreement uses in performing all or part of the Work under this Agreement must be paid not less than the applicable prevailing rate of wage for each trade or occupation as defined by the Commissioner of the State of Oregon Bureau of Labor and Industries ("BOLI") in the applicable publication entitled *Definitions of Covered Occupations for Public Works Contracts in Oregon, effective Jan1, 2018*. The prevailing wage rates for public works contracts in Oregon applicable to this GMP Amendment are contained in the following publications:

   A. January 5, 2024, *Prevailing Wage Rates*

   B. January 5, 2024 *Apprenticeship Rates*

   Such publications can be reviewed electronically at https://www.oregon.gov/boli/employers/Pages/prevailing-wage-rates.aspx and are hereby incorporated as part of the Contract Documents.

   The work will take place in Linn County, Oregon.

2. **Federal Davis Bacon Prevailing Wages.** General Decision OR20240099 dated 2/16/2024 is attached hereto.

3. In the event both state and federal rates apply to the same Work, the higher rate requirements shall control.

Exhibit S

NIH Policy Statement

See attached

NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NIH National Institutes of Health

DECEMBER 2022

INTRODUCTION

The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH recipients, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. These terms and conditions apply not only to the prime recipients, but also flow down to any subawards as well as to subrecipients unless specified otherwise in the regulation or the terms and conditions of the specific NIH award (see "Consortium Agreements" on page IIB-113).

This document also is designed to be useful to those interested in NIH grants by providing information about NIH—its organization, its staff, and its grants process. The NIHGPS is available online. This version includes many links within the document as well as links to some web resources outside of this document. Users are strongly encouraged to use the on-line version of this document to benefit from these links.

NIHGPS ORGANIZATION

The NIHGPS has three parts, which allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions:

- ***Part I: NIH Grants—General Information.*** Part I (chapters 1 and 2) contains a glossary defining commonly used terms and abbreviations used throughout the document; describes NIH and its relationship to other organizations within the Department of Health and Human Services (HHS); specifies recipient, NIH, and other HHS staff responsibilities and outlines the grant application and review processes.
- ***Part II: Terms and Conditions of NIH Grant Awards.*** Part II (chapters 3-19) includes generally applicable terms and conditions (Part IIA). This part also specifies the terms and conditions that apply to particular types of grants, recipients, and activities that differ from, supplement, or elaborate on the standard terms and conditions (Part IIB). These requirements, in separate chapters, pertain to multiple PD/PI applications and awards; construction, modernization and major alteration and renovation grants; research training grants and fellowships; career development awards; modular applications and awards; conference grants, consortium agreements; grants to foreign and international organizations (and grants with substantial foreign components awarded to domestic organizations), grants to Federal institutions and payments to Federal employees; grants to commercial organizations; and research patient care activities.
- ***Part III: Points of Contact.*** Part III (chapter 20) lists pertinent offices with their contact information.

CONVENTIONS

Certain conventions are followed throughout this document. The term “grant” is used to mean both grants and cooperative agreements; however, for clarity, certain sections mention both grants and cooperative agreements. The term “recipient” generally is used to refer to recipients of grants and cooperative agreements. “NIH” may be used in this document to refer to the entire organization or to its component organizations, or else to contrast an action by NIH, including actions by its ICs, with an action by a recipient or other organization. A reference to “Part II (IIA or IIB)” or “Part III” without further elaboration means the corresponding part of the NIH GPS.

SUPERSESSION

The NIH GPS was originally published with an effective date of October 1, 1998. It was subsequently revised several years thereafter with the turn of each new fiscal year (October). This revision of the NIH GPS is an update of the December, 2021 publication. It applies to all NIH grants and cooperative agreements for budget periods beginning on or after October 1, 2021. This version incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the GPS from December, 2021. An explanation of the major changes to the NIHGPS since the previous edition is included in the *NIH Guide for Grants and Contracts* notice announcing the reissuance of the NIH GPS.

ADDITIONAL INFORMATION

The Office of Policy for Extramural Research Administration (OPERA) develops and maintains this document. Changes in statutes, regulations, or policies that take effect before the next revision of the NIHGPS will be published separately in the *NIH Guide for Grants and Contracts*. Recipients are responsible for reviewing the *NIH Guide for Grants and Contracts* for changes and for implementing them, as appropriate. Subscribe to the *NIH Guide for Grants and Contracts* Listserv at http://-grants.nih.gov/grants/guide/listserv.htm.

TABLE OF CONTENTS

PART I: NIH GRANTS—GENERAL INFORMATION

This part contains a glossary defining terms and abbreviations commonly used throughout the NIHGPS; describes NIH and its relationship to other organizations within HHS; specifies recipient, NIH, and other HHS staff responsibilities; and outlines the grant application and review processes.

1 GLOSSARY

The glossary lists acronyms and other abbreviations used in the NIHGPS. The glossary also defines terms commonly used throughout the NIHGPS. The definitions may be amplified and additional definitions may be found throughout this document and in source documents, such as applicable statutes, grants administration regulations, and OMB circulars. This is the only location in the NIHGPS where these terms are defined. If an abbreviation used in the NIHGPS is unfamiliar, the reader should consult this list for its meaning.

1.1 ABBREVIATIONS

Exhibit 1: Abbreviation and full language of acronyms used in the Grants Policy Statement

Abbreviation	Full Meaning of Abbreviation
A&R	Alteration and Renovation
ACF	Administration for Children and Families
ACH	Automated Clearinghouse
ACL	Administration for Community Living
AHRQ	Agency for Healthcare Research and Quality
AIA	American Institute of Architects
AoA	Administration on Aging
AOR	Authorized Organization Representative
APAC	Annual Payback Activities Certification
AREA	Academic Research and Enhancement Award
ASHRAE	American Society of Heating, Refrigeration and Air Conditioning Engineers
BSO	Biological Safety Officer
CAS	Cost Allocation Services
CDA	Career Development Award
CDC	Centers for Disease Control and Prevention
CF	Common Form (previously known as Standard Form)

Abbreviation	Full Meaning of Abbreviation
CFR	Code of Federal Regulations
CGMO	Chief Grants Management Officer
CM	Construction Manager
CMS	Centers for Medicare and Medicaid Services
CoC	Certificate of Confidentiality
COR	Career Opportunities in Research Education and Training Program
CSR	Center for Scientific Review
DAB	Departmental Appeals Board
DCGP	Division of Central Grants Processing, OER, NIH
DCIS	Departmental Contracts Information System
DEA	Drug Enforcement Administration
DEITR	Division of Extramural Inventions & Technology Resources, OPERA, OER, NIH
DES	Department of Engineering Services, NIH
DFAS	Division of Financial Advisory Services, NIH
DGCO	Division of Grants Compliance and Oversight, OPERA, OER, NIH
DGP	Division of Grants Policy, OPERA, OER, NIH
DNA	Deoxyribonucleic acid
DoC	Department of Commerce
DoD	Department of Defense
DoL	Department of Labor
DPI	Division of Program Integrity, OMA, NIH
DRR	Division of Receipt and Referral, CSR
DSMB	Data and Safety Monitoring Board
EA	Environmental Assessment
FFR	Federal Financial Report
EIN	Entity Identification Number
EIS	Environmental Impact Statement
EO	Executive Order
eRA	Electronic Research Administration
ESI	Early Stage Investigator

Abbreviation	Full Meaning of Abbreviation
eSNAP	Electronic Streamlined Non-competing Award Process
F&A	Facilities and Administrative (costs)
FAC	Federal Audit Clearinghouse
FAIN	Federal Award Identification Number
FAR	Federal Acquisition Regulation
FCOI	Financial Conflict of Interest
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDP	Federal Demonstration Partnership
FEMA	Federal Emergency Management Agency
FFATA	Federal Funding Accountability and Transparency Act
FFR	Federal Financial Report (SF425)
FIC	Fogarty International Center
FICA	Federal Insurance Contributions Act
FOA	Funding Opportunity Announcement
FOI	Freedom of Information
FOIA	Freedom of Information Act
FTR	Federal Travel Regulation
FWA	Federalwide Assurance
GAAP	Generally Accepted Accounting Principles
GAGAS	Generally Accepted Government Accounting Standards
GeMCRIS	Genetic Modification Clinical Research Information System
GMO	Grants Management Officer
GMP	Guaranteed Maximum Price
GMS	Grants Management Specialist
GPO	Government Printing Office
GSA	General Services Administration
GWAS	Genome-wide Association Studies
hESC	Human Embryonic Stem Cells
HHS	U.S. Department of Health and Human Services

Abbreviation	Full Meaning of Abbreviation
HIPAA	Health Insurance Portability and Accountability Act
HIS	Indian Health Service
HPSL	Health Professional Student Loan
HRSA	Health Resources and Services Administration
HVAC	Heating, Ventilating, and Air Conditioning
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IBS	Institutional Base Salary
IC	Institute or Center
IDE	Investigational Device Exception
IHE	Institutions of Higher Education
IND	Investigational New Drug
IPA	Intergovernmental Personnel Act
IPF	Institutional Profile File
IR&D	Independent Research and Development
IRB	Institutional Review Board
IRG	Integrated Review Group
IRS	Internal Revenue Service
IVF	In vitro Fertilization
K award	Career Award
Kirschstein-NRSA	Ruth L. Kirschstein National Research Service Award
LWOP	Leave Without Pay
MARC-U*STAR	Maximizing Access to Research Careers Undergraduate Student Training in Academic Research Program
MOU	Memorandum of Understanding
MTDC	Modified Total Direct Cost
NCATS	National Center for Advancing Translational Sciences
NCT	National Clinical Trial
ND	Not Discussed
NEARC	National External Audit Review Center, OIG

Abbreviation	Full Meaning of Abbreviation
NEI	National Eye Institute
NEPA	National Environmental Policy Act
NFI	Notice of Federal Interest
NFPA	National Fire Protection Association
NHSC	National Health Service Corps
NICHD	*Eunice Kennedy Shriver* National Institute for Child Health and Human Development
NIDCR	National Institute of Dental and Craniofacial Research
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIH MSID	NIH manuscript submission reference number
NIHGPS	National Institutes of Health Grants Policy Statement
NIMH	National Institute of Mental Health
NINR	National Institute on Nursing Research
NLM	National Library of Medicine
NoA	Notice of Award
NTIS	National Technical Information Service
OASH	Office of the Assistant Secretary for Health
OCR	Office for Civil Rights, HHS
OER	Office of Extramural Research, NIH
OFCCP	Office of Federal Contract Compliance Programs, DoL
OFM	Office of Financial Management, NIH
OHRP	Office for Human Research Protections, HHS
OIG	Office of the Inspector General
OIR	Office of Intramural Research, NIH
OLAW	Office of Laboratory Animal Welfare, NIH
OMA	Office of Management Assessment, NIH
OMB	Office of Management and Budget
ONR	Office of Naval Research
OPERA	Office of Policy for Extramural Research Administration, OER, NIH
ORI	Office of Research Integrity, HHS

Abbreviation	Full Meaning of Abbreviation
OSC	Other Significant Contributor
P.L.	Public Law
PA	Program Announcement
PAR	Program Announcement with Special Review Criteria and/or Special Receipt Dates
PD/PI	Program Director/Principal Investigator
pdf	portable document format
PHS	Public Health Service
PII	Personally Identifiable Information
PMC	PubMed Central
PMCID	PubMed Central Identification/reference number
PMS	Payment Management System, Payment Management Service, HHS
PO	Program Official
PSC	Payback Service Center, NIH, or Program Support Center, HHS
PTE	Pass-through Entity
R&D	Research and Development
R&R	Research and Related
RePORT	Research Portfolio Online Reporting Tool
RFA	Request for Applications
RFP	Request for Proposals
ROTC	Reserve Officer Training Corps
RPPR	Research Performance Progress Report
S&W	Salaries and Wages
SAM	System for Award Management
SAMHSA	Substance Abuse and Mental Health Services Administration
SBA	Small Business Administration
SBC	Small Business Concern
SBIR	Small Business Innovation Research Program
SEP	Special Emphasis Panel
SEVIS	Student and Exchange Visitor Information System
SF	Standard Form

Abbreviation	Full Meaning of Abbreviation
SF424(R&R)	Standard Form 424 for Research and Research-Related (R&R)
SII	Successor-In-Interest
SNAP	Streamlined Non-competing Award Process
SO	Signing Official
SPOC	State Single Point of Contact
SRG	Scientific Review Group
SRO	Scientific Review Officer
STTR	Small Business Technology Transfer Program
TVPA	Trafficking Victims Protection Act
U.S.	United States
U.S.C.	United States Code
USCIS	United States Citizenship and Immigration Services
USDA	United States Department of Agriculture
USPS	United States Postal Service
VA	Department of Veterans Affairs
VAMC	VA Medical Center
VANPC	VA-Affiliated Non-Profit research Corporation
VAT	Value Added Tax
VHA	Veterans Health Administration
WIC	Women, Infants and Children

1.2 DEFINITION OF TERMS

Exhibit 2: Definitions of terms used in the Grants Policy Statement

Term	Definition
Acquisition cost	The cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.
Activity code	A 3-character code used to identify a specific category of extramural research activity, applied to financial assistance mechanisms. NIH uses three funding mechanisms for extramural research awards: grants, cooperative agreements and contracts. Within each funding mechanism, NIH uses 3-character activity codes (e.g., F32, K08, P01, R01, T32, etc.) to differentiate the wide variety of research-related programs NIH supports. A comprehensive list of activity codes is on the NIH web site.
Additive alternative	A use of program income earned during or after the project period that permits income that is generated under a grant to be added to funds committed to the project by the Federal awarding agency and recipient and used to further eligible project or program objectives. (See definitions for deductive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Administrative supplement	A request for (or the award of) additional funds during a current project period to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer reviewed and approved project.
Advance payment	A payment that a Federal awarding agency or pass through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the non-Federal entity disburses the funds for program purposes.
Allocation	The process of assigning a cost, or a group of costs, to one or more cost objective(s), in reasonable proportion to the benefit provided or other equitable relationship. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate cost objectives. For additional information, see Cost Considerations—The Cost Principles.

Term	Definition
Allowable cost	A cost incurred by a recipient that is: (1) reasonable for the performance of the award; (2) allocable; (3) in conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost or in the NoA as to the type or amount of cost; (4) consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; (5) accorded consistent treatment as a direct or indirect cost; (6) determined in accordance with generally accepted accounting principles; and (7) not included as a cost in any other federally supported award (unless specifically authorized by statute). For additional information on each, see Cost Considerations—The Cost Principles.
Alteration and renovation	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major or minor is made by the NIH Program Official. See definition for Modernization.
Applicable clinical trial	Applicable clinical trial is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements in FDAAA.
Applicable credit	Those receipts that offset or reduce direct or indirect costs. Typical examples of such transactions include purchase discounts, rebates, or allowances; recoveries or indemnities on losses, insurance refunds; and adjustments of overpayments or erroneous charges.
Application	A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions. (See Application Information and Processes for detailed information about the application process, including an explanation of the types of applications).
Application type code	A single-digit code identifying the type of application received and processed. Application type codes include the following: 1=New; 2=Renewal; 3=Revision; 4=Extension; 5=Non-Competing Continuation; 6=Change of Organization Status (Successor-In-Interest); 7=Change of Recipient or Training Institution; 8=Change of Institute or Division (Type 5 transfer to another NIH IC); 9=Change of Institute or Division (Type 2 transfer to another NIH IC).
Appropriation Act	The statute that provides the authority for Federal agencies to incur obligations to and make payments out of the U.S. treasury for specified purposes.
Assistance listing number	A unique number assigned to identify a Federal Assistance Listing, formerly known as the CFDA number.
Assistance listing program title	The title that corresponds to the Federal Assistance Listings Number. Formerly known as the CFDA program title.

Term	Definition
Assurance	A certification by an applicant, normally included with the application or State plan, indicating that the entity is in compliance with, or that it will abide by, a particular requirement if awarded a Federal grant.
Audit finding	Deficiencies which an auditor is required by 2 CFR Part 200.516(a) and 45 CFR Part 75.516 to report in the schedule of findings and questioned costs.
Audit resolution	The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings (that is, questioned costs).
Authorized organization representative	The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This individual is equivalent to the signing official in the eRA Commons, i.e., holds the SO Role.
Award	The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.
Awarding IC	NIH IC responsible for the award, administration, and monitoring of grant supported activities.
Budget	The financial plan for the project or program that the Federal awarding agency or pass-through entity approves during the Federal award process or in subsequent amendments to the Federal award. It may include the Federal and non-Federal share or only the Federal share, as determined by the Federal awarding agency or pass through entity. The approved budget specified in the NoA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the recipient in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.
Budget period	The time interval from the start date of a funded portion of an award to the end date of that funded portion (usually 12 months) during which recipients are authorized to expend the funds awarded, including any funds carried forward or other revisions. NIH award project periods (periods of performance) are typically divided by budget periods for budgetary and funding purposes. See Project Period. See Period of Performance.
Capital assets	Tangible or intangible assets used in operations having a useful life of more than one year which are capitalized in accordance with GAAP. Capital assets include: (1) Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, lease-purchase, exchange, or through capital leases; and (2) Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance).

Term	Definition
Capital expenditures	Expenditures to acquire capital assets or expenditures to make additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations, or alterations to capital assets that materially increase their value or useful life. (See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Capital Expenditures).
Carryover	Unobligated Federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). Obligated, but unliquidated, funds are not considered carryover.
Change in scope	An activity whereby the objectives or specific aims identified in the approved grant application are significantly changed by the recipient after award. GMO prior approval is required for a change in scope to be allowable under an award. See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Change of Scope for additional information.
Change of PD/PI	A process, usually initiated by the recipient, whereby the federally approved PD/PI is replaced by another individual, with the approval of the GMO.
Change of recipient organization	Transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).
Chief Grants Management Officer	The Grants Management Officer within an awarding agency who is the principal Grants Officer in the agency. The Chief Grants Management Officer provides leadership to an organizational component that is responsible for the business and fiscal management of an IC's grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each awarding component has a CGMO.
Claim	Depending on the context, either: (1) A written demand or written assertion by one of the parties to a Federal award seeking as a matter of right: (i) The payment of money in a sum certain; (ii) The adjustment or interpretation of the terms and conditions of the Federal award; or (iii) Other relief arising under or relating to a Federal award. (2) A request for payment that is not in dispute when submitted.

Term	Definition
Clinical research	Research with human subjects that is: 1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies. 2) Epidemiological and behavioral studies. 3) Outcomes research and health services research Studies falling under 45 CFR Part 46.101(b)(4) (the “Common Rule” prior to July 19, 2018 and 45 CFR Part 46.104(d) 4) (the “Revised Common Rule” effective July 19, 2018 Exemption 4) are not considered clinical research by this definition.

Term	Definition
Clinical trial	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. • See 45 CFR Part 46, Subpart A, referred to as the “Revised Common Rule" definition of research at 45 CFR Part 46.102(l). Pre-2018, see 45 CFR Part 46, Subpart A, referred to as the “Common Rule” definition of research at 45 CFR Part 46.102(d) • See Revised Common Rule definition of human subject at 45 CFR Part 46.102(e)(1). See Common Rule definition of human subject at 45 CFR Part 46.102(f) • The term “prospectively assigned” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignm ent of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial. • An *intervention* is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and, treatment, prevention, and diagnostic strategies. • A *health-related biomedical or behavioral outcome* is defined as the prespecified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and, well-being or quality of life Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases: Phase I. Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety. Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

Term	Definition
	Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
Closeout	The process by which the Federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the Federal award have been completed and takes actionsas described in 2 CFR Part 200.344 and 45 CFR Part 75.381.
Cluster of programs	A grouping of closely related programs that share common compliance requirements. The types of clusters of programs are research and development (R&D), student financial aid (SFA), and other clusters. “Other clusters” are as defined by OMB in the compliance supplement or as designated by a state for Federal awards the state provides to its subrecipients that meet the definition of a cluster of programs. When designating an “other cluster,” a state must identify the Federal awards included in the cluster and advise the subrecipients of compliance requirements applicable to the cluster, consistent with 2 CFR Part 200.332(a) and 45 CFR Part 75.352. A cluster of programs must be considered as one program for determining major programs, as described in 2 CFR Part 200.518, and, with the exception of R&D as described in 2 CFR Part 200.501(c) and 45 CFR Part 75.501, whether a program-specific audit may be elected.
Code of Federal Regulations	The codified regulations of the Federal government based on the final agency regulations published in the Federal Register.
Cognizant agency for audit	The Federal agency designated to carry out the responsibilities as described in 2 CFR Part 200.513 and 45 CFR Part 75.513. The cognizant agency for audit is not necessarily the same as the cognizant agency for indirect costs. A list of cognizant agencies for audit may be found at the FAC web site.
Cognizant agency for indirect costs	The Federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals developed under this part on behalf of all Federal agencies. The cognizant agency for indirect cost is not necessarily the same as the cognizant agency for audit. For assignments of cognizant agencies see the following: (1) For IHEs: 2 CFR Part 200, Appendix III, C.11. (2) For nonprofit organizations: 2 CFR Part 200, Appendix IV, C.2. (3) For state and local governments: 2 CFR Pt 200, Appendix V, F.1. (4) For Indian tribes: 2 CFR Pt 200, Appendix VII, D.1 and 45 CFR 75, Appendix VII.
Co-Investigator	An individual involved with the PD/PI in the scientific development or execution of a project. The Co-Investigator (collaborator) may be employed by, or be affiliated with, the applicant/recipient organization or another organization participating in the project under a consortium agreement. A Co-Investigator typically devotes a specified percentage of time to the project and is considered senior/key personnel. The designation of a Co-Investigator, if applicable, does not affect the PD/PI’s roles and responsibilities as specified in the NIHGPS, nor is it a role implying multiple PD/PI.

Term	Definition
Commercial organization	An organization, institution, corporation, or other legal entity, including, but not limited to, partnerships, sole proprietorships, and limited liability companies, that is organized or operated for the profit or benefit of its shareholders or other owners. The term includes small and large businesses and is used interchangeably with “for-profit organization.”
Competitive revision	A request for (or the award of) additional funds during a current project period to support new or additional activities which are not identified in the current award that reflect an expansion of the scope of the grant-approved activities. Competitive revisions require peer review.
Competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a renewal award.
Compliance Supplement	Appendix XI to 2 CFR Part 200 and 45 CFR Part 75 (previously known as the Circular A-133 Compliance Supplement). See Section 93 for HHS Agency Program Requirements.
Component	For the purposes of applications and progress reports, a component is a distinct, reviewable part of a multi-project application or progress report for which there is a business need to gather detailed information identified in the funding opportunity announcement (FOA). Components typically include general information (component organization, project period, project title, etc.), performance sites, personnel, and budget. The FOA defines the construction and naming convention for the application; the funded application defines the construction and naming convention for the progress report. Components may also be referred to as “cores” or “projects.” Note, for RPPR Question G.9, the term “foreign component” is distinct from “component” as defined here. However, a “foreign component” may also be a “component” in the RPPR. (See definition of foreign component for more information).
Computing devices	Machines used to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or ‘‘peripherals’’) for printing, transmitting and receiving, or storing electronic information. See also “supplies” and “information technology systems.”
Conference (domestic or international)	A symposium, seminar, workshop, or any other organized and formal meeting, whether conducted face-to-face or via the Internet, where individuals assemble (or meet virtually) to exchange information and views or explore or clarify a defined subject, problem, or area of knowledge, whether or not a published report results from such meeting.
Conference grant	A grant whose purpose is to support activities related to the conduct of a conference(s) or defined set of conference-related activities.

Term	Definition
Conflict of interest	Conflict of Interest is a cross-cutting issue that affects many policy areas such as peer review, financial conflict of interest, and responsible conduct of research. There are different uses of this term throughout this document. It generally means that a competing personal interest could affect, or could appear to affect, an individual's judgment or could cause the individual's impartiality to be questioned. Conflicts of Interest (actual or potential) may arise in the objective review process or in other activities or phases of the financial assistance process. See also Financial Conflict of Interest for a specific definition covering that policy area.
Consortium agreement	A formalized agreement whereby a research project is carried out by the recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific level of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. The relationship between the recipient and the collaborating organizations is considered a subaward relationship. (See Consortium Agreements chapter in IIB).
Construction	Construction of a new building structure or facility, including the installation of fixed equipment, which provides space not presently available. It excludes the purchase of land and ancillary improvements, for example, parking lots or roads. The construction of shell space is not allowable as a construction activity since shell space does not provide usable space for research activities).See Construction chapter in IIB.
Consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, recipients and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants also include firms that provide professional advice or services. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Consultant Services).
Contact PD/PI	When multiple PD/PIs are designated, NIH requires that the applicant organization identify one of the PD/PIs as the Contact PD/PI to serve as a primary point of contact. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. See Multiple PI chapter in IIB for additional information.

Term	Definition
Contract	A legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. The term as used in 2 CFR Part 200 and 45 CFR Part 75 does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward. See Subaward.
Contractor	An entity that receives a contract. See contract.
Cooperative agreement	A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302–6305: (1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or pass through entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal government or pass-through entity's direct benefit or use; (2) Is distinguished from a grant in that it provides for substantial involvement between the Federal awarding agency or pass-through entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. (3) The term does not include: (i) development agreement as defined in 15 U.S.C. 3710a; or (ii) An agreement that provides only: (A) Direct United States Government cash assistance to an individual; (B) A subsidy; (C) A loan; (D) A loan guarantee; or (E) Insurance.
Cost allocation plan	Central service cost allocation plan or public assistance cost allocation plan.
Cost objective	A program, function, activity, award, organizational subdivision, contract, or work unit for which cost data are desired and for which provision is made to accumulate and measure the cost of processes, products, jobs, capital projects, etc. A cost objective may be a major function of the non-Federal entity, a particular service or project, a Federal award, or an indirect (Facilities & Administrative (F&A)) cost activity, as described in 2 CFR Part 200, Subpart E—Cost Principles.
Cost overrun	Any amount charged in excess of the Federal share of costs for the project period (competitive segment).
Cost principles	The government-wide principles established under 2 CFR Part 200 and 45 CFR Part 75 for determining the allowable costs incurred by non-Federal entities under Federal awards. The principles are for the purpose of cost determination and are not intended to identify the circumstances or dictate the extent of Federal Government participation in the financing of a particular program or project. The principles are designed to provide that Federal awards bear their fair share of cost recognized under these principles except where restricted or prohibited by statute. In the case of hospitals, they follow the cost principles in 2 CFR Part 200, Appendix IX, "Hospital Cost Principles." In the case of commercial organizations, there are no cost principles specifically applicable; the cost principles for commercial organizations are set forth in the FAR (48 CFR Part 31.2). See Cost Considerations—The Cost Principles for additional details.
Cost sharing	See matching or cost sharing definition.

Term	Definition
Cost sharing or matching alternative	An alternative use of program income whereby income accrued during the period of grant support may be used to satisfy a cost sharing or matching requirement. (See also definitions for additive alternative and deductive alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Cost-type contract	A contract or subcontract under a grant in which the contractor or subcontractor is paid on the basis of the allowable costs it incurs, with or without a fee.
Data and safety monitoring plan	For each NIH-supported clinical trial, NIH requires a data and safety monitoring plan that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the awarding IC for approval prior to the accrual of human subjects.
Data Management	The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.
Data Management and Sharing Plan (DMS Plan)	A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.
Data Sharing	The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.
Debarment and suspension	The actions taken by a debarring official in accordance with OMB guidance at 2 CFR Part 180, "Non-procurement Debarment and Suspension," as implemented by HHS in 2 CFR Part 376, to exclude a person or organization from participating in grants and other non-procurement awards government-wide. If debarred or suspended, the person or organization may not receive financial assistance (under a grant, cooperative agreement, or subaward, or contract under a grant) for a specified period of time. Debarments and suspensions carried out pursuant to 2 CFR Part 376 are distinct from post-award suspension action by an awarding agency. (See also Public Policy Requirements and Objectives—Debarment and Suspension).
Debt collection	The process of collecting funds owed by recipients to the Federal government, which, under grants, generally are owed as a result of formal cost disallowances.
Debt instrument	A document used to record a legal obligation of one party to pay a financial obligation to another in accordance with predetermined terms and conditions.

Term	Definition
Deductive alternative	An alternative for the use of program income earned during the period of grant support under which allowable costs of the project or program to be paid by the Federal government are offset by the amount of the program income. (See also definitions for additive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Departmental Grants Appeals Board	The independent office established in the Office of the Secretary with delegated authority from the Secretary to review and decide certain disputes between recipients of HHS funds and HHS awarding agencies under 45 CFR Part 16 and to perform other review, adjudication and mediation services as assigned.
Deviation	A departure on a single-case or class basis from a regulatory or policy requirement. A single-case deviation represents a request for waiver or exception sought for one grant only that arises on a case-by-case basis. A class deviation involves more than one grant for which the same type of deviation action is being requested.
Direct costs	Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
Disallowed costs	Those charges to a Federal award that the Federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable Federal statutes, regulations, or the terms and conditions of the Federal award.
Discretionary Award	An award in which NIH, in keeping with its statutory authority to exercises judgement ("discretion"), selects the recipient and/or the amount of funding through a competitive process. Generally, NIH awards are discretionary. See Non-Discretionary Award.
Domestic organization	A public (including a State or other governmental agency) or private non-profit or commercial organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.
Early Stage Investigator	An individual who is classified as a New Investigator and is within 10 years of completing their terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). See definition of New Investigator.
Entity Identification Number	A three-part coding scheme of 12 characters used in PMS to identify organizations and individuals. The first character identifies the recipient as an organization or an individual. The next nine characters are the Employer Identification Number. The last two characters are a suffix to provide distinction between organizational entities that are assigned a single EIN and those that have more than one. (Also known as Payment System Identifier.)

Term	Definition
Equipment	Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000. (See also capital assets, computing devices, general purpose equipment, information technology systems, special purpose equipment, and supplies).
eRA Commons	The Electronic Research Administration (eRA) Commons is a virtual meeting place where NIH extramural recipient organizations, recipients, and the public can receive and transmit information about the administration of biomedical and behavioral research. The eRA Commons is divided into both unrestricted and restricted portions that provide for public and confidential information, respectively.
Expanded authorities	A standard term of all NIH awards to allow recipients several flexibilities to waive the requirement for prior approval for specified actions. NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances for certain awards. (see Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award).
Expenditure report	Means: (1) For non-construction grants, the SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report); (2) for construction grants, the SF-271 “Outlay Report and Request for Reimbursement” (or other OMB-approved equivalent report)

Term	Definition
Expenditures	Charges made by a non-Federal entity to a project or program for which a Federal award was received. 1. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. 2. For reports prepared on a cash basis, expenditures are the sum of: i. Cash disbursements for direct charges for property and services; ii. The amount of indirect expense charged; iii. The value of third-party in-kind contributions applied; and iv. The amount of cash advance payments and payments made to subrecipients. 3. For reports prepared on an accrual basis, expenditures are the sum of: i. Cash disbursements for direct charges for property and services; ii. The amount of indirect expense incurred; iii. The value of third-party in-kind contributions applied; and iv. The net increase or decrease in the amounts owed by the non-Federal entity for: A. Goods and other property received; B. Services performed by employees, contractors, sub-recipients, and other payees; and C. Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.
Facilities and Administrative (F&A) costs (or indirect costs)	Necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of F&A (indirect) costs. F&A (indirect) cost pools must be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived.
Federal agency	An ‘‘agency’’ as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552 (f).
Federal Audit Clearinghouse (FAC)	The clearinghouse designated by OMB as the repository of record where non-Federal entities are required to transmit the reporting packages required by Subpart F—Audit Requirements of 2 CFR Part 200 Subpart F – Audit Requirements and 45 CFR Part 75 Subpart F. The mailing address of the FAC is Federal Audit Clearinghouse, Bureau of the Census, 1201 E. 10th Street, Jeffersonville, IN 47132/. Any future updates to the location of the FAC may be found at the OMB web site.

Term	Definition
Federal award	Depending on the context, in either paragraph (1) or (2) of this section: (1)(i) The Federal financial assistance that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 2 CFR Part 200.101 and 45 CFR Part 75.101; or (ii) The cost-reimbursement contract under the Federal Acquisition Regulations that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 2 CFR Part 200.101 and 45 CFR Part 75.101. (2) The instrument setting forth the terms and conditions. The instrument is the grant agreement, cooperative agreement, other agreement for assistance covered in paragraph (2) of Federal financial assistance, or the cost-reimbursement contract awarded under the Federal Acquisition Regulations. (3) Federal award does not include other contracts that a Federal agency uses to buy goods or services from a contractor or a contract to operate Federal government owned, contractor operated facilities (GOCOs). (4) See also definitions of Federal financial assistance, grant agreement, and cooperative agreement.
Federal award date	The date when the Federal award is signed by the authorized official of the Federal awarding agency.
Federal Award Identification Number	A unique number assigned to a financial assistance award to assist recipients in correctly reporting subawards. The public can use the FAIN and the Assistance listing number together to find one accurate result when searching on line in such databases as USASpending.gov and FSRS. The FAIN can be found on the notice of award. NIH implements the FAIN by deriving it from the core elements of the grant number. For example, the FAIN for 1R0lHL654321-01 would be R01HL654321.
Federal awarding agency	The Federal agency that provides a Federal award directly to another entity. See also Awarding IC.
Federal Demonstration Partnership	A cooperative initiative among some Federal agencies, including NIH, selected organizations receiving Federal funding for research, and certain professional associations. Its efforts include demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs.

Term	Definition
Federal financial assistance	1. Federal financial assistance means assistance that non-Federal entities receive or administer in the form of: i. Grants; ii. Cooperative agreements; iii. Non-cash contributions or donations of property (including donated surplus property); iv. Direct appropriations; v. Food commodities; and vi. Other financial assistance (except assistance listed in paragraph (b) of this section). 2. For 2 CFR Part 200.202 and 2 CFR Part 200 Subpart F and 45 CFR Part 75, Subpart F, federal financial assistance also includes assistance that non-Federal entities receive or administer in the form of: i. Loans; ii. Loan Guarantees; iii. Interest subsidies; and iv. Insurance. 3. Federal financial assistance does not include amounts received as reimbursement for services rendered to individuals as described in 2 CFR Part 200.502(h) and (i) also see and 45 CFR Part 75.502.
Federal institution	A Cabinet-level department or independent agency of the executive branch of the Federal government or any component organization of such a department or agency. For the purposes of this document, this term is used in the context of a Federal institution as a recipient. See also Awarding IC.
Federal interest	For purposes 2 CFR Part 200.330 and 45 CFR Part 75.343 or when used in connection with the acquisition or improvement of real property, equipment, or supplies under a Federal award, the dollar amount that is the product of the: (1) Federal share of total project costs; and (2) Current fair market value of the property, improvements, or both, to the extent the costs of acquiring or improving the property were included as project costs.
Federal program	1. All Federal awards which are assigned a single number in the Assistance listings. 2. When no Assistance listing number is assigned, all Federal awards to non- Federal entities from the same agency made for the same purpose should be combined and considered one program. 3. Notwithstanding paragraphs (1) and (2) of this definition, a cluster of programs. The types of clusters of programs are: i. Research and development (R&D); ii. Student financial aid (SFA); and iii. ‘‘Other clusters,’’ as described in the definition of Cluster of Programs.

Term	Definition
Federal share	The portion of the total project costs that are paid by Federal funds.
Federalwide Assurance	The Federalwide Assurance is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under a FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR Part 46, as well as the terms of assurance.
Fee	An amount, in addition to actual, allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as profit. (See Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowable Costs and Fee—Profit or Fee).
Financial conflict of interest	A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. See 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought and Public Policy Requirements and Objectives—Financial Conflict of Interest.
Foreign component	The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are: • collaborations with investigators at a foreign site anticipated to result in co-authorship; • use of facilities or instrumentation at a foreign site; or • receipt of financial support or resources from a foreign entity. Foreign travel for consultation is not considered a foreign component. (See Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components chapter in IIB).

Term	Definition
Foreign organization	An entity that is: 1. A public or private organization located in a country other than the United States and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance; 2. A private nongovernmental organization located in a country other than the United States that solicits and receives cash contributions from the general public; 3. A charitable organization located in a country other than the United States that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entities organized primarily for religious purposes; or 4. An organization located in a country other than the United States not recognized as a *Foreign Public Entity*.
Foreign public entity	(1) A foreign government or foreign governmental entity; (2) A public international organization, which is an organization entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (22 U.S.C. 288–288f); (3) An entity owned (in whole or in part) or controlled by a foreign government; or (4) Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.
For-profit organization	An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. A for-profit organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons. (Also see definition for small business concern).
Full-time appointment	The number of days per week and/or months per year representing full-time effort at the applicant/recipient organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.
Funding opportunity announcement	A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names (including Notices of Funding Opportunity (NOFO), as described in 2 CFR Part 200) depending on the Agency and type of program. Funding opportunity announcements can be found at grants.gov and in the *NIH Guide for Grants and Contracts*.

Term	Definition
General purpose equipment	Equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles. See also "Equipment" and "Special Purpose Equipment."
Generally Acceptable Accounting Principles (GAAP)	The meaning specified in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).
Generally Accepted Government Auditing Standards (GAGAS)	Also known as the Yellow Book, generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits.
Grant number	A grant number is a unique identifier for a grant composed of the application type code, activity code, Institute code, 6-digit serial number, support year and /or suffix code for the support year of the grant, or other information, such as a supplement (S1), resubmission (A1), or a fellowship's institutional allowance. In Federalwide systems (e.g., USASpending.gov, FFATA/FSRS) the Federal Award Identifier Number (FAIN) is used to identify grants for Federalwide implications. Similar to the NIH Grant Number, the FAIN consists of the activity code, Institute code, and 6-digit serial number. Sample Grant Number: 1 R01 AI 123456-01 A1 S1 Sample FAIN: R01 AI 654321

Term	Definition
Grant or grant agreement	A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302, 6304: 1. Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or passthrough entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal awarding agency or pass-through entity's direct benefit or use; 2. Is distinguished from a cooperative agreement in that it does not provide for substantial involvement between the Federal awarding agency or passthrough entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. 3. Does not include an agreement that provides only: i. Direct United States Government cash assistance to an individual; ii. A subsidy; iii. A loan; iv. A loan guarantee; or v. Insurance. See also Cooperative Agreement.
Grants Management Officer	An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. GMOs are delegated the authority from the CGMO to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards. See also Chief Grants Management Officer definition.
Grants Management Specialist	An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to recipients; and administering grants after award.
Grants.gov	Grants.gov has been designated by the Office of Management and Budget as the single access point for all grant programs offered by 26 Federal grant-making agencies. It provides a single interface for agencies to announce their grant opportunities and for all applicants to find and apply for those opportunities.

Term	Definition
Grant-supported project or activity	Those activities specified or described in a grant application or in a subsequent submission that are approved by an NIH IC for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.
Honoraria	Payments given in support of professional services for the purpose of conferring distinction or to symbolize respect, esteem, or admiration. In other words, if the service is related to research oversight, research supervision, co-authoring research papers, then the payments are not honoraria but considered research funding.
Hospital	A facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state. Also includes a non-profit or commercial hospital or a medical care provider component of a non-profit organization (for example, a foundation).
Human Fetal Tissue	Human Fetal Tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as NIH guidance. See also Human Fetal Tissue from Elective Abortion.
Human subject	Revised Common Rule (45 CFR Part 46, effective July 19, 2018): A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Pre-2018 Common Rule (45 CFR Part 46, effective July 19, 2018): A living individual about whom an investigator (whether professional or student) conducting research: (i) Data through intervention or interaction with the individual; or (ii) Identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. (See Public Policy Requirements and Objectives—Human Subjects Protections).

Term	Definition
Impact score	The impact score is the rating which is assigned to an individual application by an SRG and designates the reviewers' assessment of scientific and technical merit of the application. For research projects, this is defined as the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of established review criteria. The impact score is one mechanism by which the SRG makes a recommendation to the funding component concerning the application's scientific and technical merit. Impact scores may be numeric (10 – 90) or alphabetical (ND, for example).
Improper payment	(1) Any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and (2) Includes any payment to an ineligible party, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except for such payments where authorized by law), any payment that does not account for credit for applicable discounts, and any payment where insufficient or lack of documentation prevents a reviewer from discerning whether a payment was proper.
Indian tribe (or "federally recognized Indian tribe")	Any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)). See annually published Bureau of Indian Affairs list of Indian Entities Recognized and Eligible to Receive Services.
Indirect costs	See facilities and administrative costs definition.
Information technology systems	Computing devices, ancillary equipment, software, firmware, and similar procedures, services (including support services), and related resources. See also computing devices and equipment.
Innovation	Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of innovation would be new medical or biological products for improved value, efficiency, or costs.
Institute or Center	The NIH organizational component responsible for a particular grant program or set of activities. The terms "NIH IC," or "awarding IC" are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award.

Term	Definition
Institutional Animal Care and Use Committee	The *PHS Policy on Humane Care and Use of Laboratory Animals* incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). IACUC review and approval is required for all PHS supported activities involving live vertebrate animals prior to funding.
Institutional base salary	The annual compensation paid by an organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties for the applicant/recipient organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages).
Institutional Review Board (IRB)	An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.
Institutions of Higher Education (IHEs)	IHE is defined at 20 U.S.C. 1001.
Intangible property	Property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible).
Intergovernmental Personnel Act (IPA)	The Intergovernmental Personnel Act Mobility Program provides for the temporary assignment of personnel between the Federal Government and state and local governments, colleges and universities, Indian tribe (or "federally recognized Indian tribe" governments, federally funded research and development centers, and other eligible organizations. The goal of the Intergovernmental Personnel Act mobility program is to facilitate the movement of employees, for short periods of time, when this movement serves a sound public purpose.

Term	Definition
Internal control over compliance requirements for Federal awards	A process implemented by a non-Federal entity designed to provide reasonable assurance regarding the achievement of the following objectives for Federal award: 1. Transactions are properly recorded and accounted for, in order to: i. Permit the preparation of reliable financial statements and Federal reports; ii. Maintain accountability over assets; and iii. Demonstrate compliance with Federal statutes, regulations, and the terms and conditions of the Federal award; 2. Transactions are executed in compliance with: i. Federal statutes, regulations, and the terms and conditions of the Federal award that could have a direct and material effect on a Federal program; and ii. Any other Federal statutes and regulations that are identified in the Compliance Supplement; and 3. Funds, property, and other assets are safeguarded against loss from unauthorized use or disposition.
Internal controls	A process, implemented by a non-Federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: (1) Effectiveness and efficiency of operations; (2) Reliability of reporting for internal and external use; and (3) Compliance with applicable laws and regulations.
International organization	An organization that identifies itself as international or intergovernmental and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.
Invention reporting	The requirement pursuant to 37 CFR Part 401 that recipients of contracts, grants or cooperative agreements fully disclose any subject inventions made during the performance of work under a funding agreement in order to protect the Federal government's rights.
Investigational new drug	A new drug or biological drug that is used in a clinical investigation.
Investigator-initiated research	Research funded as a result of an investigator, on their own, submitting a research application in response to Parent Announcements only. Also known as unsolicited research.
IPF number	Institutional Profile File (IPF) number is a unique number used by NIH for tracking/reporting awards to recipient institutions.

Term	Definition
Just-in-Time	NIH policy allows the submission of certain elements of a competing application to be deferred until later in the application process, after review when the application is under consideration for funding. Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by NIH. Through this module, institutions can electronically submit the information that is requested after the review, but before award. See Completing the Pre-Award Process—Just-In-Time Procedures for additional information.
Liquidated damages	An amount defined in a contract and chargeable against funds due to the contractor for each day the contractor fails to complete the project beyond the contract completion date.
Local government	Any unit of government within a state, including a: (1) County; (2) Borough; (3) Municipality; (4) City; (5) Town; (6) Township; (7) Parish; (8) Local public authority, including any public housing agency under the United States Housing Act of 1937; (9) Special district; (10) School district; (11) Intrastate district; (12) Council of governments, whether or not incorporated as a nonprofit corporation under state law; and (13) Any other agency or instrumentality of a multi-, regional, or intra-state or local government.
Major A&R	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants. See "Modernization" on page I-34.
Matching or cost sharing	The portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute). This may include the value of allowable third party in-kind contributions, as well as expenditures by the recipient.
Mechanism	Extramural awards are divided into three types of financial assistance: *grants*, *cooperative agreements* and *contracts*. A mechanism is the type of funded application or transaction used by NIH. Within each mechanism NIH includes programs. Programs can be further refined by specific activity codes.
Merger	A legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for the recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change will apply.
Metadata	Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).

Term	Definition
Micro-purchase	A purchase of supplies or services using simplified acquisition procedures, the aggregate amount of which does not exceed the micro-purchase threshold. Micro-purchase comprise a subset of a non-Federal entity's small purchases. Micro-purchase threshold means the dollar amount at or below which a non-Federal entity may purchase property or services using micro-purchase procedures (see § 2 CFR Part 200.320). Generally, the micro-purchase threshold for procurement activities administered under Federal awards is not to exceed the amount set by the FAR at 48 CFR Part 2, Subpart 2.1, unless a higher threshold is requested by the non- Federal entity and approved by the cognizant agency for indirect costs (For NIH DCA for non-profits or DFAS for commercial organizations).
Minor A&R	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. See "Modernization" on the next page. Minor A&R is not an allowable activity or cost under grants to individuals or grants for limited purposes, such as grants in support of scientific meetings (conference grants). Routine maintenance and repair of the organization's physical plant or its equipment is not considered A&R; these types of costs are typically treated as F&A costs.

Term	Definition
Modernization	Modernization. Alteration, renovation, remodeling, improvement, expansion or repair of, or completion of shell space in an existing building (whether for storage or for human occupancy), necessary to make the building suitable for use for the purposes of a particular program. Modernization is distinct from construction in that it leaves the existing structure in place. This can range from updating flooring to replacing everything except for the existing mainframe and foundations. When the primary purpose of the award is to modernize biomedical research facilities, the grant cannot support the conduct of any research. Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants. Examples of activities of Major A&R are as follows: • A structural change (e.g. to the foundation, roof, floor or exterior load-bearing walls of a facility, or extension of an existing facility) to increase the floor area and/or change the function and purpose of a facility Examples of activities of Minor A&R are as follows: • Changes to physical characteristics (interior dimensions, surfaces, and finishes); internal environments (temperature, humidity, ventilation, and acoustics); or utility services (plumbing, electricity, gas, vacuum, and other laboratory fittings); • Installation of fixed equipment (including casework, fume hoods, large autoclaves, biological safety cabinets); • Replacement, removal, or reconfiguration of interior non-load bearing walls, doors, frames, or windows in order to place equipment in a permanent location; • Making unfinished shell space suitable for purposes other than human occupancy, such as storage of pharmaceuticals; or • Alterations to meet requirements for accessibility by physically disabled individuals.
Modified Total Direct Cost (MTDC)	All direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subawards up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.

Term	Definition
Modular application	A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review of the application, award, and post-award administration.
Monitoring	A process whereby the programmatic and business management performance aspects of a grant are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources.
Name change	An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.
New Investigator	A PD/PI who has not previously competed successfully as a PD/PI for a substantial independent research award is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains their status as a New Investigator. A complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at http://grants.nih.gov/grants/new_investigators/#definition. See also the definition of Early Stage Investigator.
No-cost extension	An extension of time to a project period and/or budget period to complete the work of the grant under that period, without additional Federal funds or competition. See NIH Standard Terms of Award and Prior Approval Requirements.
Non-competing continuation application/award	A financial assistance request (in the form of an application or progress report) or resulting award for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applicants.
Non-Discretionary Award	An award made by NIH to specific recipients in accordance with statutory, eligibility and compliance requirements, in which NIH has no ability to exercise judgement. The award amount could be determined specifically or by formula. NIH does not typically make non-discretionary awards. See "Discretionary Award" on page I-19.
Non-Federal entity	A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a Federal award as a recipient or subrecipient.
Non-Federal share	When cost sharing or matching is required as a condition of an award, the portion of allowable project/program costs not borne by the Federal government.
Non-profit organization	Any corporation, trust, association, cooperative, or other organization, not including IHEs, that: (1) Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; (2) Is not organized primarily for profit; and (3) Uses net proceeds to maintain, improve, or expand the operations of the organization.

Term	Definition
Notice of Award	The official, legally binding document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: 1. notifies the recipient of the award of a grant; 2. contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and, 3. provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.
Obligations	When used in connection with a non- Federal entity's utilization of funds under a Federal award, obligations means orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the non- Federal entity during the same or a future period.
Office of Management and Budget (OMB)	The Executive Office of the President, Office of Management and Budget.
Offset	IC or awarding agency approval/authorization of the use of unobligated grant funds remaining from a prior budget period to support grant activities of the current budget period. An offset does not change the current budget period authorized amount of funding but does reduce the amount of current fiscal year funds provided to support the authorized award amount.
OMB Circulars	Government-wide guidance issued to Heads of Federal agencies by the Director of OMB. OMB Circulars directly pertinent to grants include the following: • cost principles (OMB Circular A-21, OMB Circular A-87, and OMB Circular A-122). See Cost Considerations—The Cost Principles for additional information; • uniform administrative requirements (OMB Circular A-102 and OMB Circular A-110); • audit requirements for non-profit organizations (OMB Circular A-133). See Monitoring—Audit for additional information. These Circulars were superseded by OMB's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("Uniform Guidance") and were implemented in HHS regulation at 2 CFR Part 200.
Open Researcher and Contributor Identifiers (ORCID iDs)	Unique, persistent digital identifiers that distinguish individual investigators and can be used to connect researchers with their contributions to science over time and across changes of name, location, and institutional affiliation. These free identifiers are assigned and maintained by the non-profit organization ORCID.
Organization	A generic term used to refer to an Institution of Higher Education or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.

Term	Definition
Other Significant Contributors	Individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition.
Other support	Includes all resources made available to researcher or senior key personnel in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. Other support does not include training awards, prizes, start-up support from the US based institution, or gifts. (note: Gifts are resources provided where there is no expectation of anything (e.g.., time, services, specific research activities, money, etc.) in return).
Oversight agency for audit	The Federal awarding agency that provides the predominant amount of funding dir-ectly (direct funding) (as listed on the schedule of expenditures of Federal awards, see 2 CFR Part 200.510(b)) to a non-Federal entity unless OMB designates a specific cognizant agency for audit.. When the direct funding represents less than 25 per-cent of the total Federal expenditures (as direct and subawards) by the non-Federal entity, then the Federal agency with the predominant amount of total funding (direct and subawards) is the designated cognizant agency. When there is no direct fund-ing, the Federal awarding agency which is the predominant source of pass-through funding must assume the oversight responsibilities. The duties of the oversight agency for audit and the process for any reassignments are described in 2 CFR Part 200.513(b) and 45 CFR Part 75.513.
Parent announcement	NIH-wide FOA enabling applicants to electronically submit an investigator-initiated grant application for a specific activity code, e.g., Research Project Grant (Parent R01).
Participant support costs	Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects. For the purposes of Kirschstein-NRSA programs and Education Grants (e.g., R25), this term does not apply. NIH will continue to use the terms trainees, trainee-related expenses, and trainee travelfor those programs.
Pass-through entity	A non- Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.

Term	Definition
Payback	Requirement that the recipient of a NRSA postdoctoral fellowship engage in qualified health-related research, health-related research training, or health-related teaching activities for a length of time equal to the period of NRSA support received. Only the first year of training incurs a payback obligation. In general, payback activity must involve at least 20 hours per week and be conducted over 12 consecutive months; special exceptions may be considered on a case-by-case basis. See Ruth L. Kirschstein National Research Service Awards—Payback for additional information.
Payment Management System	The HHS centralized grants payment system operated by the Payment Management Service, Program Support Center. Most HHS (and some other Federal government agencies') recipients receive grant payments through this system.
Peer review	The two-stage process that involves the consistent application of standards and procedures that produce fair, equitable, timely, and objective examinations of applications based on an evaluation of scientific or technical merit or other relevant aspects of the application. The review is performed by experts (Peer Reviewers) in the field of endeavor for which support is requested. Peer review is intended to provide guidance and recommendations to the NIH individuals responsible for making award decisions.
Period of performance	The total estimated time interval between the start of an initial Federal award and the planned end date, which may include one or more funded portions, or budget periods. Identification of the period of performance (project period) in the Federal award does not commit the awarding agency to fund the award beyond the currently approved budget period. The period of performance for NIH awards is noted on the Notice of Award. See "Project period" on page I-40. See "Budget period" on page I-10.
Person months	The metric for expressing the effort (amount of time) PD/PI(s), faculty and other senior/key personnel devote to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year, academic year, and/or summer term; and the organization's definition of such. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment.
Personal property	Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities.

Term	Definition
Personally Identifiable Information (PII)	Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public web sites, and university listings. This type of information is considered to be Public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual.
Phase III clinical trial	As defined by NIH, a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included. (See clinical trial definition).
Pre-award costs	Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant's own risk, for otherwise allowable costs.
Prior approval	Written approval by an authorized HHS official, e.g., a designated IC GMO, evidencing prior consent before a recipient undertakes certain activities or incurs specific costs (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).
Profit	See definition for fee.
Program	A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs that carry out their missions through the award of grants or cooperative agreements to other organizations.

Term	Definition
Program Director/Principal Investigator	The individual(s) designated by the applicant organization/recipient to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the official(s) at the applicant organization/recipient, or as appropriate, to a collaborating organization for the proper conduct of the project, program, or activity including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI.
Program income	Gross income earned by the non-Federal entity that is directly generated by a sup-ported activity or earned as a result of the Federal award during the period of per-formance except as provided in 2 CFR Part 200.307(f) and 45 CFR Part 75.307. (See Period of performance.) Program income includes but is not limited to income from fees for services performed, the use or rental or real or personal property acquired under Federal awards, the sale of commodities or items fabricated under a Federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See 2 CFR Part 200.307, 45 CFR Part 200.307, 2 CFR Part 200.407 and 45 CFR Part 75.407 and 35 USC §§ 200-212 for inventions made under Federal awards. (See Administrative Requirements—Management Systems and Procedures—Program Income).
Program Official/Program Officer/Project Officer	The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant or cooperative agreement.
Progress report	Periodic, usually annual, report submitted by the recipient and used by NIH to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report. This report may also be called the non-competing continuation progress report.
Project period	The total time for which Federal support of a project has been programmatically approved as shown in the NoA; however, it does not constitute a commitment by the Federal government to fund the entire period. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a renewal award(s), and extensions. See "Period of performance" on page I-38. See "Budget period" on page I-10.
Project/performance site	Location(s) of where the work described in the research plan will be conducted.
Property	Real property or personal property.

Term	Definition
Protected Personally Identifiable Information (Protected PII)	An individual's first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother's maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed. (See Personally Identifiable Information (PII)).
Questioned cost	A cost that is questioned by the auditor because of an audit finding: 1. Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of a Federal award, including for funds used to match Federal funds; 2. Where the costs, at the time of the audit, are not supported by adequate documentation; or 3. Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances.
Real property	Land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment.
Recipient	An entity, usually but not limited to non-Federal entities, that receives a Federal award directly from a Federal awarding agency. The term recipient does not include subrecipients nor consortiums of the award. See Non-Federal entity.
Renewal application	An application requesting additional funding for a period subsequent to that provided by a current award. Renewal applications compete for funds with all other peer reviewed applications, and must be developed as fully as though the applicant is applying for the first time. The previous NIH term was "competing continuation."
Renewal award	An award made subsequent to an expiring Federal award for which the start date is contiguous with, or closely follows, the end of the expiring Federal award. A renewal award's start date will begin a distinct period of performance.
Research & Development (R&D)	All research activities, both basic and applied, and all development activities that are performed by HHS award recipients. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. ''Research'' is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. ''Development'' is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.
Research Administrator	The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. See also Roles and Responsibilities—Recipient Staff.

Term	Definition
Research misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. 1. Fabrication is making up data or results and recording or reporting them. 2. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. 3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. 4. Research misconduct does not include honest error or honest differences of opinion.
Research patient care costs	Costs of routine and ancillary services provided by hospitals to participants in research protocols.
Responsible party	Responsible party is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to refer to the entity or individual who is responsible under FDAAA for registering a clinical trial and submitting clinical trial information to ClinicalTrials.gov.
Resubmission application	An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. Applicants must make significant changes to the application and can only resubmit once the summary statement is available from review of the first submission. Applicants must apply and undergo peer review. Additional policies on resubmissions can be found in the applicable Application Instruction Guide. The previous NIH term was "revision." A resubmission has a suffix in its application identification number, e.g., A1.
Revision application	As defined in the Federalwide SF424 (R&R): An application that proposes a change in 1) the Federal Government's financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. Note in general for NIH applicants, #2 would not require the submission of another application. NIH recipients use revision applications to request an increase in support in a current budget period for expansion of the project's approved scope or research protocol. Applicants must apply and undergo peer review. The previous NIH term was "competing supplemental." NOTE: The former NIH term "revision," is now "resubmission". A revision has a suffix in its application identification number; e.g., S1.
Scientific Data	The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.

Term	Definition
Scientific Review Group (SRG)	A peer review committee group of primarily non-government experts (peer reviewers), qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review, to evaluate and give expert advice on the scientific and technical merit of the applications. No more than one-fourth of the members of any SRG may be Federal employees, as noted in 42 CFR Part 52(h).
Scientific Review Officer (SRO)	The NIH official who serves as the designated Federal officer having legal responsibility for managing the peer review meeting, the procedures for evaluating the applications assigned to the SRG and the determinations and management of conflicts of interest, as noted in 42 CFR Part 52(h).
Scope of work	The aims, objectives, and purposes of a grant; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the grant's objectives. This includes the research or training plan included with the original grant application, along with any approved modifications.
Senior/Key Personnel	The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel.
Significant rebudgeting	A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.
Simplified acquisition threshold	The dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures in order to expedite the purchase of items costing less than the simplified acquisition threshold. The simplified acquisition threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1. (See also Micro-purchase.)
Small business concern	A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the SBA at 13 CFR Part 121.

Term	Definition
Special purpose equipment	Equipment which is used only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers. See also Equipment and General purpose equipment.
State	Any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments.
State government	The government of any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. For purposes of NIH grants, federally recognized Indian tribal governments generally are considered State governments. State institutions of higher education and State hospitals are not considered State governments for HHS's general administrative requirements for grants and the NIHGPS.
Stipend	A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.
Subrecipient	A non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. The term includes consortium participants.
Subsidiary	An entity in which more than 50 percent of the entity is owned or controlled directly by a parent corporation or through another subsidiary of a parent corporation.
Successor-in-interest	Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
Supplies	All tangible personal property other than those described in Equipment. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or $5,000, regardless of the length of its useful life. See Computing devices and Equipment.

Term	Definition
Suspension of award activities	An action by the NIH awarding IC requiring the recipient to cease all activities on the award pending corrective action by the recipient. It is a separate action from suspension under HHS regulations (2 CFR Part 376) implementing Executive Orders 12549 and 12689. (See Public Policy Requirements and Objectives—Debarment and Suspension and Administrative Requirements—Enforcement Actions).
Termination	The ending of a Federal award, in whole or in part at any time prior to the planned end of period of performance.
Terms and conditions of award	All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The NoA may include both standard and specific award conditions that are considered necessary to attain the grant's objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the Federal government's interests.
Third-party in-kind contributions	The value of non-cash contributions (i.e., property or services) that: (1) Benefit a federally assisted project or program; and (2) Are contributed by non-Federal third parties, without charge, to a non- Federal entity under a Federal award.
Total costs	The total allowable costs (both direct costs and F&A costs) incurred by the recipient to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the recipient to satisfy a matching or cost-sharing requirement.
Unique Entity Identifier (UEI)	The identifier assigned by the System for Award Management (SAM) to uniquely identify business entities.
United States	The 50 States, territories, and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.
Unliquidated obligations	For financial reports prepared on a cash basis, obligations incurred by the non-Federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-Federal entity for which an expenditure has not been recorded.
Unobligated balance	The amount of funds authorized under a Federal award that the non-Federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-Federal entity's unliquidated obligations and expenditures of funds under the Federal award from the cumulative amount of the funds that the Federal awarding agency or pass-through entity authorized the non-Federal entity to obligate.
Withholding of support	A decision by NIH not to make a non-competing continuation award within the current competitive segment.

2 THE NATIONAL INSTITUTES OF HEALTH AS A GRANT-MAKING ORGANIZATION

NIH is the steward of medical and behavioral research for the Nation. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH operates under the general policy guidance of the Department in carrying out its mission, which is accomplished through the conduct and support of biomedical and behavioral research, research training, research infrastructure, and communications. These efforts take place intramurally (primarily at NIH) and extramurally (through grants, cooperative agreements, and contracts awarded to institutions of higher education, governmental organizations, non-profit research organizations, commercial organizations, and individuals). NIH also works closely with other HHS components and other Federal departments and agencies. HHS components include SAMHSA, FDA, CDC, IHS, AHRQ, HRSA, ACF, ACL, OASH, and CMS, among others.

The rules that govern grants and cooperative agreements detailed at 2 CFR Part 200 and 45 CFR Part 75 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements), and in certain cases further codified through HHS regulation, provide the framework for the terms and conditions of NIH awards, as specified in "Part II: Terms and Conditions of NIH Grant Awards" on page IIA-1.

NIH is organized into ICs, which have their own mission and functions, separate appropriations, and statutory authorities. The ICs that award grants and their points of contact are listed in Part III. Although the ICs operate under the same general grant process and requirements, applicants and recipients need to be aware of differences that may exist. This information may be obtained from NIH IC staff. The policies generally applicable to NIH grants are set forth in the NIHGPS.

2.1 ROLES AND RESPONSIBILITIES

NIH, as a Federal grantor agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for recipient organizations.

The following subsections highlight the major functions and areas of responsibility of Federal and recipient staffs. NIH recognizes that additional staff members in a number of different organizations may be involved in grant-related activities; however, this section details only the major participants representing the Federal government and the recipient. The responsibilities of CSR and IC staff members, who are involved only in the initial review phase of the peer review process, are described in The Peer Review Process—Initial Review—Responsibilities. The responsibilities of other offices, such as OHRP, are described in Part II as applicable.

2.1.1 NIH and HHS Staff

The roles and responsibilities of NIH and HHS participants are as follows:

- ***Grants Management Officer.*** The GMO whose name appears in the NoA is the NIH official responsible for the business management and other non-programmatic aspects of the award. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to applicants and recipients, including interpretation of grants administration policies and provisions; and administering and closing out grants. The GMO works closely with their counterparts in other NIH ICs and with the designated PO. The GMO is the focal point for receiving and acting on requests for NIH prior approval or for changes in the terms and conditions of award, and is the only NIH official authorized to obligate NIH to the expenditure of Federal funds or to change the funding, duration, or other terms and conditions of award. A Chief Grants Management Officer is the principal GMO who provides leadership to an organizational component that is responsible for the business and fiscal management of the ICs grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each awarding component has a CGMO.
- ***Grants Management Specialist.*** The GMS whose name appears in the NoA is an agent of the GMO and is assigned responsibility for the day-to-day management of a portfolio of grants.
- ***Program Official.*** The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with CSR/IC SROs; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the GMO. The PO and the GMO work as a team on many of these activities.
- ***Scientific Review Officer.*** SROs are health science administrators who manage the activities of SRGs, including CSR study sections. The SRO is responsible for conduct of the SRG in accordance with applicable laws, regulations, and policies. For the SRG for which they are responsible, the SRO reviews applications for completeness and conformity to requirements, ensures that adequate numbers of reviewers with appropriate expertise are available for application review, assigns applications to individual reviewers as discussion leaders and for preparation of written critiques, manages conflicts of interest and confidentiality, and serves as the overall point of contact with applicants during the initial phase of the peer review process, i.e., until the conclusion of the SRG meeting.
- ***Other NIH, HHS and Federal Agency Staff.*** In addition to the GMO and PO, the recipient may be required to interact with other NIH or HHS staff members or offices with respect to its organization-wide systems and/or individual transactions. These include the office responsible for negotiating F&A costs and research patient care rates, typically the cognizant CAS office, ONR, or DFAS; OIG; OHRP; ORI; OLAW; and OPERA. Staff members in these offices generally coordinate with the GMO, but they are responsible for discrete areas of specialization and are not required to channel their communications with the recipient through the GMO. Part III includes a list of these organizations and their addresses and telephone numbers. ONR is the cognizant agency for negotiation of F&A costs for some NIH recipients.

2.1.2 Recipient Staff

Overall responsibility for successfully implementing an NIH grant is a shared responsibility of the PD/PI (s), the AOR, and the Research Administrator. As key members of the grant team, they respectively lead the scientific and administrative aspects of the grant. While communications can be conducted with Research Administrators and other institutional staff, NIH staff members conduct official business only

with the designated PD/PI(s) and AORs. The roles and responsibilities of recipient participants are as follows:

- ***Authorized Organization Representative***. The AOR is the designated representative of the recipient organization in matters related to the award and administration of its NIH grants, including those that require NIH approval. The AOR should ascertain and assure that the materials the applicant organization are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used by other individuals in the preparation and submission of a similar grant application. In signing a grant application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the grant application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the grant-supported project or activities resulting from the application. (Also see Legal Implications of Applications.) This individual also is responsible to NIH for ensuring that the organization complies with applicable Federal laws and regulations, including required certifications and assurances, its application, and the terms and conditions of individual awards. For applications submitted electronically through Grants.gov, the signature of the AOR is documented as part of the electronic submission process and is authenticated through the Grants.gov registration process. In the eRA Commons, this individual holds the Signing Official role. Although NIH requires that the recipient organization designate such an official, NIH does not specify the organizational location or full set of responsibilities for this official.
- ***Program Director/Principal Investigator.*** A PD/PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award. The applicant organization may designate multiple individuals as PD/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the recipient organization or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one identified PD/PI on an application diminishes neither the responsibility nor the accountability of any individual PD/PI.

  When a single PD/PI is designated, that individual is not required to be an employee of the applicant organization. However, because the grant, if awarded, is made to the organization, the applicant organization must have a formal written agreement with the PD/PI that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PD/PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant, if awarded.

  When multiple PD/PIs are designated, NIH requires identification of one PD/PI who will be designated as the Contact PD/PI. This person is responsible for communication between the PD/PIs and NIH. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. They are not required to be an employee of the applicant organization. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. This same principle applies to all PD/PIs at the applicant organization; e.g., they need not be employees; however the applicant organization must have a formal written agreement in place.

When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but need not be employees. Any consortium agreement must address the unique aspects to these individuals holding the PD/PI role.

PD/PIs are members of the recipient team responsible for ensuring compliance with the financial and administrative aspects of the award. They work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. NIH encourages PD/PIs to maintain contact with the NIH PO with respect to the scientific aspects of the project and the GMO/GMS concerning the business and administrative aspects of the award. The NIH staff contacts list includes contact information for NIH grants management and program staff at each IC.

- ***Research Administrator***. The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. Depending on the structure of the organization, this individual can be located centrally or within an organizational component such as a Department.

2.2 ERA COMMONS

eRA Commons is an online interface where grant applicants, recipients and Federal staff at NIH and grantor agencies can conduct their research administration business electronically as well as access and share administrative information relating to research grants. While applicants use Grants.gov to find and apply for grants; the eRA Commons retrieves the application or proposal information from Grants.gov, compiles it into a consistent application format and then makes it available to applicants and NIH staff for electronic research administration purposes.

Access to the eRA Commons is vital for all steps in the NIH grant administration process. Following application submission, the eRA Commons becomes the primary site for accessing grant information such as Institute/Center assignments, review outcomes, Summary Statements, and Notices of Award. The eRA Commons also provides electronic business processes such as Internet Assisted Review, submission of Just-In-Time material, submission of electronic SNAP progress reports (eSNAP), submission of notification of extensions without funds, and submission of Closeout documents. Appropriate user roles are assigned to registered individuals depending on the responsibilities assigned to them by the recipient organization.

2.2.1 eRA Commons Registration

An organization and PD/PI(s) must complete a **one-time** registration in the Commons. Institutional/organizational officials are responsible for registering PD/PI(s) in the eRA Commons. PD/PI(s) should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: Organizations registering in the eRA Commons for the first time should allow 2-4 weeks to complete the registration process.

2.2.1.1 eRA Commons Registration for the Organization

Prospective applicant organizations should also see Legal Implications of Applications before beginning the eRA Commons registration process.

Organizations may verify their current registration status by running the "Commons Registered Organizations" query. This query can be run without logging into the Commons. The resulting list includes organization name and location and the NIH-assigned IPF Code that has been stored in the institutional profile for that organization.

To register an Organization in the eRA Commons an AOR should follow the procedures found on the Register in eRA Commons page.

Once an organization is registered, information in the Institutional Profile can be maintained through the Commons.

During this registration process, NIH may make a preliminary assessment of applicant organization eligibility. Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH may deny registration if an organization is determined ineligible. Note, acceptance of an organization's registration in the Commons does not mean an organization is an acceptable recipient for a particular program. That assessment will be made by the NIH awarding component prior as part of the pre-award process. See Determining Applicant Organization Eligibility for additional information.

Foundations that represent already existing recipient organizations, or a newly formed consortium where the consortium members are already individually recognized as NIH recipient organizations present unique and complex situations and should contact the Systems Policy Branch, OPERA before attempting to separately register as a new applicant organization.

2.2.1.2 eRA Commons Registration for the PD/PI

The individual(s) designated as the PD/PI(s) on the application must also be registered in the Commons. The PD/PI(s) must hold a PI eRA Commons role **and** be affiliated with the applicant organization. **The initial registration must be done by an AOR who has the SO role in the Commons or other authorized accounts administrators at the organization**. However, after the initial registration process is complete, it becomes the responsibility of each individual to maintain the information in their personal profile.

Designating the PI role in the eRA Commons provides the individual with the administrative authority needed to see pertinent information regarding an application (e.g., summary statements, scores, electronic submission status, etc.). The PI role within the eRA Commons is necessary to complete the grant application process, to view the impact score and summary statement (the SO role also has this capability), and if an award is made, to complete required post-award actions such as submission of a progress report. The PD/PI may delegate certain authorities to other individuals.

Users should only have one PD/PI eRA Commons account. If the PD/PI has already been registered in eRA Commons by an organization other than the organization submitting an application, a separate eRA Commons registration with the submitting organization is not necessary. However, the submitting organization must take steps to affiliate the individual with that organization so that the individual can view and access data records for those applications.

For more information on the features of the eRA Commons, including links to resources such as user guides and frequently asked questions, see the eRA Commons webpage.

2.2.1.3 eRA Commons Registration for Other Individuals Participating in NIH Progress Reports

Any individual with an Undergraduate, Graduate Student, and/or Postdoctoral Role who participates in a NIH-funded project for at least one person month or more should also be registered in the eRA Commons and should verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. This is required regardless of whether salary is actually charged to the project. For graduate students supported on a particular research grant, this could include project roles of graduate research assistant or graduate student. For postdoctoral individuals supported on a particular research grant, this could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

When an individual is assigned the Undergraduate, Graduate Student, or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482. The Commons user name ID for those with an Undergraduate, Graduate Student, or Postdoctoral Role is not required at the time of application submission, but will be required as part of the Research Performance Progress Report (RPPR).

For individuals at the postdoctoral level, this requirement is already in effect and progress reports will not be accepted if the Commons ID is not provided. For individuals at the undergraduate and graduate student levels, a Commons ID is required with RPPRs. The Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now.

Note, the Graduate Student and Postdoctoral eRA Commons Roles should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions. Nor should they be used for individuals supported on institutional training grants and reported using xTrain; the Trainee Role must continue to be used for those individuals.

In addition to the above roles, a Commons ID is required at the time of submission for sponsors in fellowship applications, component leads on multi-project applications, candidates for support under Research Supplements to Promote Diversity in Health-Related Research (Diversity Supplements), and primary mentors on career development applications. A Commons ID is also required at the time of application submission for all individuals listed on the R & R Senior / Key Person Profile (Expanded) Form; the requirement applies to Senior/Key Personnel as defined in NIHGPS Section 1.2 as well as Other Significant Contributors (OSCs). For other roles a Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

2.3 APPLICATION INFORMATION AND PROCESSES

This section provides an overview of NIH's grant support mechanisms, types of entities eligible to receive grants, types of applications, types of funding opportunities, legal implications of applications, policies affecting application preparation and submission, application forms, application receipt information and deadlines, fraud, waste and abuse of NIH grant funds, and availability and confidentiality of application information.

2.3.1 Support Mechanisms

NIH ICs award grants under multiple programs and subprogram initiatives and use a variety of support mechanisms. NIH grants may be distinguished by purpose, type of recipient, amount, or other

characteristics. One method NIH uses to differentiate the various support mechanisms is an activity coding that indicates the category and specific form of support (e.g., R01, F32, P01, R43). The applicability of requirements may vary for different activity codes. Some of the distinctions also are significant for purposes of applying Part II. NIH ICs may vary in the way they use specific activity codes; not all ICs accept applications for all types of grant programs and may apply specialized eligibility criteria. See a comprehensive list of activity codes on NIH's web .

2.3.2 Eligibility

In general, NIH grants may be awarded to organizations that are domestic or foreign, public or private, or non-profit or commercial. Eligible organizations include governments, including Federal institutions, institutions of higher education, other non-profit organizations, hospitals, and, in rare occasions, individuals (see Completing the Pre-Award Process—Determining Applicant Organization Eligibility). Any special criteria for applicant eligibility or requirements concerning the qualifications of the PD/PI or other staff or participants will be specified in the FOA, program guidelines, or other publicly available documents. Part IIB includes information on fellow and trainee eligibility.

2.3.3 Types of Award Instruments

NIH uses several different extramural award instruments in support of its mission. NIH grants and cooperative agreements are financial assistance instruments. Under a cooperative agreement, NIH expects to be substantially involved in carrying out the project. Grants are used both for investigator-initiated research and for more targeted research. Cooperative agreements generally do not result from investigator-initiated applications. The NIHGPS pertains to grants and cooperative agreements; however, NIH may apply terms and conditions that differ from those in the NIHGPS consistent with the nature of its involvement under cooperative agreements.

2.3.4 Types of Applications

In the NIH grants process, five types of applications are used most frequently. The first four application types described below are considered “competing” because, through the peer review process, the application must compete for available funding with other applications.

- ***New Application (Type 1).*** A request for financial assistance for a project or activity that is not currently receiving NIH support and must compete for support. A new application is being submitted for the first time.
- ***Renewal (Type 2).*** A request for additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be fully developed as though the applicant is applying for the first time.

- ***Revision (Type 3).*** A request for an increase in support in a current budget period for expansion of the project's approved scope or research protocol. The request may specify budgetary changes required for the remainder of the project period as well as for the current budget period. Applications for revisions are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. A revision application should not be submitted until after the original application has been awarded and may not extend beyond the term of the current award period. A revision application must have the same title as the currently funded grant. (A Type 3 prefix also refers to a request/award for a non-competing administrative supplement [see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Need for Additional NIH Funding without Extension of Budget and Project Period.]).
- ***Resubmission.*** An unfunded application that the applicant has modified following initial review and resubmitted for new consideration. Before a resubmission application can be submitted, the PD/PI must have received the summary statement from the previous review. A resubmission application may be submitted for any of the three preceding types of applications provided an appropriate funding opportunity announcement is available. See Application Information and Processes—Policies Affecting Applications for other policies affecting Resubmissions. NIH allows only one resubmission application.
- ***Non-Competing Continuation Progress Report (Type 5).*** A non-competing progress report is required to continue support of a PHS grant for the second or subsequent budget period within an approved competitive segment (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

In addition to the list above, NIH periodically uses a pre-application (also known as a "white paper" or "précis") to facilitate certain approaches or economies, such as reducing burden on the applicant community, for a funding opportunity. Pre-applications are generally used in combination with a competing application in a 2-phase process. Pre-applications do not result in an award; the end result is the opportunity to submit to the subsequent phase of a particular program. Successful applicants to the pre-application phase are notified of the opportunity to submit to the subsequent phase. In addition to the pre-application, NIH may use an application process for prospective applicants to request access to an NIH research resource. This process also does not result in an award; the end result is permission to access a resource. NIH uses the numbers shown in parentheses as prefixes to distinguish the application types and any resulting awards (e.g., 5R0198765-02 is a non-competing continuation progress report).

2.3.5 Types of Funding Opportunity Announcements (FOAs)

The majority of applications submitted to NIH under the categories of research and research training (including fellowships) are investigator-initiated. NIH accepts applications on the application due dates noted on the submission schedule. NIH generally reviews applications in three review cycles per year; however any variations in schedule will be noted in the FOA. Some ICs review applications for Institutional National Research Service Awards (T32) only once a year; such information is generally found in a particular FOA. The schedules for submission, review, and award of investigator-initiated applications are available on NIH's web site.

Funding Opportunity Announcement (FOA). A FOA is a publicly available document in which a Federal agency makes known its intentions to award "Discretionary Award" on page I-19, usually as a result of competition for funds. FOAs may be program announcements, requests for applications, notices of funding availability, solicitations, or other identifiers depending upon the agency and type of program and each FOA will outline the program goals and objectives. All applications must be submitted in

response to a FOA regardless if the submission is electronic or on paper. FOAs include information to allow prospective applicants to determine whether to apply.

NIH FOAs primarily fall into the categories of Program Announcements, Requests for Applications and Parent Announcements. While individual announcements will continue to carry an announcement number reference to PA or RFA, all announcements are FOAs. This general term is used to reference any type of funding announcement. NIH uses the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

- ***Program Announcement (PA).*** A PA is a formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time using standard peer review processes. NIH may also make funds available through PARs (PAs with special receipt, referral, and/or review considerations) and PASs (PAs with set-aside funds).

ICOs issuing PARs or PASs may now choose to describe within the FOA criteria that would make an application non-responsive to the PAR/PAS. Only applications to PARs and PASs that include non-responsive criteria will be evaluated by the ICOs upon receipt for non-responsiveness. These non-responsive criteria will be listed in the Funding Opportunity Description section (Part 2, Section 1). Those applications that are deemed non-responsive will be withdrawn from review.

PAs may be used for any support mechanism other than construction awards. Unless otherwise specified in the PA, new applications (and associated renewal and revision applications) submitted in response to PAs are treated as investigator-initiated. PAs also are used to annually solicit applications for the SBIR and STTR programs. Those applications must be received by the dates specified in the PA.

- Notices of Special Interest (NOSI). A NOSI succinctly highlights a specific topic of interest, such as a specific area of research or program. It then directs applicants to one or more active FOAs (often parent announcements) for submission of applications for the initiative described.

- ***Request for Applications (RFA).*** An RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s). For cooperative agreements, the RFA will describe the responsibilities and obligations of NIH and recipients as well as joint responsibilities and obligations. Applications submitted in response to an RFA are usually reviewed by an SRG specially convened by the awarding component that issued the RFA.
- ***Parent Announcements.*** Electronic submission of applications requires that applications must be associated with a specific FOA. Therefore, NIH omnibus parent announcements are provided for applicants to submit investigator-initiated (unsolicited) applications. Responding to such an omnibus or umbrella parent FOA ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. This process in no way diminishes the interest of NIH ICs in investigator-initiated, unsolicited research grant applications. Parent announcements are NIH-wide, but some ICs may limit their participation; therefore prospective applicants should check the announcement to determine IC participation. For institute-specific opportunities in a particular area of science, search the *NIH Guide for Grants and Contracts*.

All applications involving one or more clinical trials must be submitted through a FOA specifically designed for clinical trials. NIH will not process applications that propose one or more clinical trials if the FOA (Part 2, Section 2) indicates clinical trials are “Not Allowed.” Applications that propose clinical trials, including applications with a mix of trial and non-trial aims or a combination of clinical and non-clinical studies, must be submitted to FOAs designated as clinical trial “Optional” or “Required".

All NIH FOAs are published in the *NIH Guide for Grants and Contracts* and on Grants.gov under Search Grants (https://www.grants.gov/web/grants/search-grants.html). NIH may develop areas of high priority or special research interest and use a special announcement to stimulate submission of applications in those areas. These announcements are also published as FOAs in the *NIH Guide for Grants and Contracts*.

2.3.6 Legal Implications of Applications

An applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates in order to be considered for support. The signature of an AOR on the application certifies that the organization will comply with all applicable assurances and certifications referenced in the application. The applicant organization is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application, including the F&A cost (indirect cost) rate. The AOR’s signature further certifies that the applicant organization has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

Applicants for and recipients of NIH grant funds, whether such funds are received through a grant, indirectly under a contract or consortium agreement, or by a fiscal agent acting on another organization’s behalf, or as student assistance under a training grant, are responsible for and must adhere to all applicable Federal statutes, regulations, and policies, including income tax regulations. Questions concerning the applicability of income tax regulations to grant funds should be directed to the IRS. The applicant also is expected to be in compliance with applicable State and local laws and ordinances.

Applicants may be required to provide proof of organizational eligibility (such as proof of non-profit status), trainee or fellow eligibility and citizenship, or other eligibility information. Applications also must demonstrate compliance (or intent to comply), through certification or other means, with a number of public policy requirements. The more significant of the public policy requirements for the purpose of peer review are those concerning research involving human subjects; inclusion of genders, members of minority groups, and individuals across the lifespan in clinical research; and research involving live vertebrate animals. Part II details public policy requirements and cost and administrative policies.

There are times when an institution desires to use a Foundation or other similar organization to provide administrative services for NIH grants. These situations are often complex and each situation is unique when determining which organization is the appropriate applicant institution. Foundations, particularly those associated with institutions already recognized as NIH recipient organizations, should contact DGP, OPERA before attempting to separately register as an applicant organization.

Similarly, when new consortiums are formed where the consortium members are already separately recognized as NIH recipient organizations, DGP, OPERA should be contacted before attempting to separately register as a new applicant organization.

2.3.7 Policies Affecting Applications

Application information to be submitted typically includes a project description, budget and budget justification, biographical sketches of senior/key personnel, and other information specified in the application instructions, in the announcement, and/or in program guidelines, if any. Applicants should consult the cost principles and general administrative requirements for grants pertaining to their organizational type in order to prepare the budget and complete other parts of the application. This section describes NIH policies that affect application preparation and/or submission. Specific details on application content are addressed in application instructions and specific FOAs. Any significant change to the application post-submission must be reported immediately to the appropriate NIH official.

2.3.7.1 Applications That Include Consortium/Contractual F&A Costs

For FOAs that include a direct cost limit, NIH policy excludes consortium/contractual F&A when determining if an applicant is in compliance with the direct cost limitation. This policy extends to all solicited and investigator-initiated applications and to all active announcements (Request for Applications and Program Announcements), involving consortium/contractual F&A costs, regardless of budget amount or budget format (e.g., modular and non-modular). While consortium F&A costs may be requested and awarded, applicants should not consider these costs when determining if a budget exceeds a direct cost limit.

This policy impacts eligibility to submit a modular budget. The modular budget format is used for applications requesting $250,000 or less in direct costs per year. Consortium/contractual F&A costs are not factored into this direct cost limit; however, they may be requested in addition to the $250,000.

This policy also impacts applications requesting a budget of $500,000 direct costs or more for any year. These applications require prior approval from Institute/Center staff; however, the limit is exclusive of any consortium F&A costs. It does not affect any specific FOA that includes a total cost limit.

This policy does not affect the SBIR and STTR programs since the statutory budget guidelines are based on total costs, not direct costs.

2.3.7.2 Acceptance for Review of Unsolicited Applications Requesting $500,000 or More in Direct Costs

Any applicant requesting $500,000 or more in direct costs (excluding consortium F&A costs) in any one budget period is required to contact the IC PO, in writing or by telephone, as early as possible during development of the application but no later than 6 weeks or as specified in the funding opportunity announcement before submission for prior approval. If staff is contacted less than six weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than $500,000, then approval should be sought even earlier. This requirement applies to a single grant application, whether a new, renewal, revision, or resubmission application, under any NIH support mechanism; it also applies to a group of applications, such as those for clinical trial networks, meeting the $500,000 threshold in the aggregate even if no single application in the group requests that much.

This policy does not apply to applications submitted in response to RFAs or to other announcements that include specific budgetary limits. However, any such application must be responsive to budgetary limits specified or NIH will administratively withdraw the application and it will not be reviewed or considered for funding.

The PD/PI must include a cover letter with the application identifying the PO contacted and the IC that has agreed to accept assignment of the application. CSR will accept such applications for review only if an IC has agreed to accept the application for consideration and the applicant submits with its application

a cover letter to that effect with the name of the authorizing program staff member and IC affiliation (see The Peer Review Process). An application subject to this policy that does not include the required information in the cover letter will be administratively withdrawn and will not be reviewed or considered for funding.

2.3.7.3 Resubmission of Unfunded RFA Applications

This policy applies to all activity codes that might be solicited via an RFA and to instances where there is a change in activity code. Unless a particular FOA states that resubmissions from an RFA may be submitted, unfunded applications should be submitted as **new** applications if the grant applications fall into the following categories:

1. Applications that were originally submitted in response to an RFA and now submitted as an investigator-initiated application.
2. Applications that were originally submitted as investigator-initiated applications and subsequently submitted in response to an RFA.
3. Applications that were originally submitted using one grant activity code and subsequently submitted using a different grant activity code (for example, an application that was originally an R01 and is now submitted as an R21).

The new application must be submitted on the scheduled due dates for new applications and follow all instructions that apply to new applications. Do not include an Introduction describing the changes and improvements made; do not mark text to indicate the changes and do not mention prior review anywhere in the application (including the cover letter). In these cases the reviewers will not be provided with the previous summary statement.

2.3.7.4 Submission of Resubmission Application

NIH will accept a new (A0) application following an unsuccessful resubmission (A1) application or a prior A0 application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review. NIH's policy for accepting overlapping applications remains in effect: NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that NIH will not review:

1. a new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping resubmission (A1) application.
2. a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
3. an application that has substantial overlap with another application pending appeal of initial peer review (see Section 2.3.9.4 below)

NIH policy allows a thirty-seven month window for one resubmission (A1) following the submission of a new, renewal, or revision application (A0 application). The initial submission of a new, renewal or revision application constitutes the starting point for the thirty-seven month policy. After thirty-seven months, NIH views a submission as a new application, regardless of whether an unsuccessful resubmission (A1) was submitted during the thirty-seven month time period.

Submission to a different FOA under review at the same time is not sufficient to make an application new. (There are exceptions for applications following an RFA or changing activity code. See Resubmission of Unfunded RFA Applications above). The new application must be submitted on the scheduled

due dates for new applications. It must not include an Introduction describing the changes and improvements made; and the text must not be marked to indicate the changes.

2.3.7.5 New Investigators and Early Stage Investigators

The NIH is committed to identifying and attracting new biomedical researchers and will continue to explore novel ways to encourage early transition to independence. NIH has implemented a number of policies specific to New Investigators, and in particular the category of New Investigator called Early Stage Investigator.

New Investigator. In general, a PD/PI is considered a New Investigator if they have not previously competed successfully as PD/PI for a substantial independent research award. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. See definitions section for additional information and references.

Early Stage Investigator (ESI). An ESI is a New Investigator who is within 10 years of completing their terminal research degree or is within 10 years of completing medical residency (or the equivalent). Extensions of the end of ESI eligibility date may be requested following the procedures documented on the New Investigator web site.

The NIH intends to support New Investigators at success rates comparable to those for established investigators submitting new applications. ESIs should comprise a majority of the New Investigators supported. Where possible, New Investigator applications will be clustered during review. The applications will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator.

NIH New Investigator policies are limited to applications for traditional research project grant (R01) support. Accordingly, NIH strongly encourages New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding. To determine New Investigator and Early Stage Investigator status, NIH relies on the data entered by the individual in their eRA Commons Profile, therefore it is important that PD/PIs verify the accuracy of their personal profiles. Particularly key for ESIs are the terminal research degree and end date of residency data fields. ESI status and end of eligibility date also appear in the Commons profile for the individual.

2.3.7.6 Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance

The applicant organization is required to secure and retain a unique signature and dated assurance from the PD/PI for each submitted application, prior to submitting an application to the NIH. This assurance must be available to the NIH or other authorized DHHS or Federal officials upon request. Such an assurance must include at least the following certifications: 1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; 2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and 3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. If multiple PIs are proposed in an application, this assurance must be retained for all named PIs.

For individual Fellowship applications, this assurance requirement applies to the individual fellow and the sponsor. Such an assurance must include at least the follow certifications: (1) that the information submitted within the application is true, complete and accurate to the best of the Fellow's and Sponsor's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Fellow and Sponsor to criminal, civil, or administrative penalties; (3) that the Sponsor will provide appropriate training, adequate facilities, and supervision if a grant is awarded as a result of the application; (4) that the

Fellow has read the Ruth L. Kirschstein National Research Service Award Payback and will abide by the Assurance if an award is made; and (5) that the award will not support residency training. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

2.3.7.7 Post-Submission Grant Application Materials

Post-submission of application materials is not required. Adding materials to reviewer workload may be counterproductive, so applicants should carefully consider the need to send post-submission materials. For materials that are submitted after the initial grant application submission but prior to initial peer review, NIH will only accept such materials resulting from unforeseen administrative issues. This policy does not modify the Just-in-Time requirements or any other requests for additional information after the initial peer review.

Allowable Post-Submission Materials for All Applications

For all research and research-related applications, individual fellowship, and individual career development awards, acceptable materials include:

- Citations of issued patents
- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution [e.g., Program Director/Principal Investigator (PD/PI) moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Special submission procedures are required for videos.
- Other post-submission materials specified in the FOA for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application, which must include only**:
    - List of authors and institutional affiliations
    - Title of the article
    - Journal or citation (if available)

Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the Funding Opportunity Announce- ment (FOA) for which the application was submitted or a special Guide Notice.

Additional Materials for Certain Applications

Institutional Training and Training-related Grants (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2): in addition to the materials for All Applications above, news—since the training grant application was submitted—of:

- a trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- a faculty member's promotion, funding, or publications; and
- the addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).

Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications: in addition to the materials for All Applications listed above:

- New information on the Sponsor/Mentor funding, limited to the project title, funding source (e.g., NIH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
- News of change in Mentor(s) or other Senior/Key Persons specified in the original application.

Applications submitted to Requests for Applications (RFAs): the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

Conference Grant Applications (R13, U13): a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

Any other types of post-submission materials are not likely to be accepted.

Requirements for Submitting Post-Submission Materials

All post-submission materials must conform to NIH policies on font size, margins, and paper size as referenced in the applicable application instructions.

- Any specified formats (e.g., budgets, biographical sketches) and page limits referenced in the applicable application instructions apply.
- If post-submission material is not required on a specific format page and does not have a specified page limit, each explanation or letter is limited to one page.
- If the application has multiple components (subprojects or cores), each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page.

Post-submission materials must be received by the NIH Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. Post-submission materials will not be accepted if fewer than 30 calendar days remain before the peer review meeting, unless specifically stated otherwise in the FOA for which the application was submitted or in a special Guide Notice.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the post-submission materials may originate from the PD/PI, Contact PD/PI, or

organ- izational officials, the AOR must send the materials directly to the SRO or must send their concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

Post-submission materials **can only** be submitted as a PDF attachment, except for video submissions. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check their application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

Non-traditional Application Materials

NIH will accept only videos as non-traditional application materials. No devices or other media will be accepted unless specified in the Funding Opportunity Announcement (FOA). However, videos may include demonstrations of devices and other items as listed below. These guidelines may be superseded by instructions in specific FOAs.

The only acceptable content for videos is demonstrations of devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change.

- Examples of acceptable content include unusual interventions or surgical procedures, prototype model use, visualization of 3-D structures or structural changes in molecules or cells, software or database demonstrations, educational materials or video games.
- Examples of unacceptable content include virtual tours of laboratories, equipment in place, platform presentations, advertisements, commercials, or PowerPoint presentations [unless requested by the Scientific Review Officer (SRO) in lieu of a site visit].

Application requirements. The application must be structured at the time of submission to indicate that a video will be submitted subsequently. The cover letter submitted with the application must include information about the intent to submit a video; if this is not done, a video will not be accepted. Key images/“stills” and a brief description of each video must be included within the page limits of the research strategy. Sufficient descriptive information must be provided within the research strategy to understand the information presented in the video, as not all reviewers may be able to access the video, depending on technological constraints.

When human subjects or personally identifiable information is represented in a video, the applicant organization is responsible for ensuring that human subjects have been consented and protected appropriately. Submission through the Authorized Organizational Representative (AOR) certifies acceptance of this responsibility.

Video formats. Multiple videos may be submitted per application but their aggregate length must not exceed 2 minutes for single-project applications and 5 minutes for multi-component applications.

Post-submission videos can be submitted as an mp4, mov, avi, or wmv video format with a maximum file size of 25 MB. This material can be submitted on CD/DVD or via e-mail and it will be uploaded to the grant folder by the SRO.

Closed captioning is not required when narration is present. However, captioning is recommended as an optional component of the video to assist reviewers evaluating the application.

Limitations. Video files containing unacceptable content or exceeding the time or size limits will not be accepted. Applications submitted with hyperlinks to videos or with videos embedded in the research strategy will be considered in violation of page limits and the application will be withdrawn before review.

Note: Due to technological constraints, the NIH cannot guarantee that reviewers will be able to view videos.

Video submission. If the submission requirements have been met (see above), videos will be accepted by the SRO managing the review. After the assignment of the application to a review group is visible in the eRA Commons, the applicant should contact the SRO for that review group to discuss logistics for submission of any videos.

As with all other post-submission materials, videos must be received by the SRO one month (30 calendar days) prior to the peer review meeting or as otherwise specified in the FOA. Videos will not be accepted if fewer than 30 calendar days remain before the peer review meeting.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the video may originate from the Program Director/Principal Investigator (PD/PI), Contact PD/PI for multiple PD/PI applications, or organizational officials, the AOR must send the materials directly to the SRO, or must send their concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

The opportunity to submit additional materials should not be a means of circumventing submission deadlines, page limitations, or content requirements and should not substantially enhance, alter or add to the originally submitted application.

After the initial peer review phase is completed, the Chief GMO of the IC is the NIH official responsible for accepting additional materials. Most of the material submitted after peer review can be submitted as part of the Just-in-Time process.

2.3.7.8 SAM Registration and Unique Entity Identifier (UEI) Requirements

All applicant organizations must register in the System for Award Management (SAM) and maintain the registration with current information at all times during which such organizations have an application under consideration for funding by NIH and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. SAM is the central repository for common government-wide certifications and representations required of NIH applicants and recipients. Additional information about registration procedures may be found at the SAM.gov internet site.

A Unique Entity Identifier (UEI) is issued as part of the SAM.gov registration process. The UEI must be provided on application forms; the same UEI must be used for all registrations, as well as on the grant application.

2.3.7.9 Graduate Student Compensation

The maximum amount NIH will award for the support of a graduate student on a research grant or a cooperative agreement is tied to the National Research Service Award (NRSA) zero-level stipend in effect at the time the grant award is issued on the Federal award date. The schedule for NRSA stipends can be found on NIH's web site. Consistent with cost principles for Institutions of Higher Education (IHEs) described in 2 CFR Part 200.431(j) and 200.466 and 45 CFR Part 75.466 and 45 CFR Part 75.431, the compensation of graduate students supported by research grants must be reasonable. The amount provided for compensation includes salary or wages, fringe benefits, and tuition remission.

These guidelines apply to graduate students at the recipient institution who are supported by NIH research grants and cooperative agreements and not to individuals supported by NRSA training grants

and fellowships. NIH has separate appropriations to support research training under the NRSA authorization at Section 487 of the Public Health Service Act.

The stipends provided to recipients of NRSA support offset the cost-of-living during the period of training and are not considered equivalent to salaries or other forms of compensation provided to individuals supported on research grants. Nevertheless, the entry-level postdoctoral NRSA stipend provides a useful benchmark for an award amount that approximates a reasonable rate of compensation for graduate students. Expected future increases in NRSA stipends, to adjust for inflation, should permit annual increases in the maximum award for such individuals.

For all new and competing grant and cooperative agreement awards, the NIH will provide reasonable amounts for graduate compensation, consistent with the requested budget for the position(s) and up to the currently effective NRSA zero postdoctoral stipend level. NIH staff will review the compensation requested for graduate students on competing and cooperative agreement applications for which a detailed budget is submitted. NIH will neither request nor accept budgets for those applications using a modular budget format solely for the purpose of reviewing graduate student compensation. However, applicants should use this policy when estimating the number of modules.

When submitting detailed budgets that request support for a graduate student, recipients are reminded to request actual institutional-based compensation and to provide information justifying the requested compensation level. If this information is not provided, NIH staff will obtain this information from the institution's business office for any request that appears excessive.

NIH Institutes and Centers will review the requested compensation level and, if considered reasonable, will award the actual amount requested, up to a maximum equal to the NRSA zero level postdoctoral stipend. Revised budgets submitted solely to adjust requested levels for graduate students will not be accepted.

Institutions may continue to rebudget funds to charge more than the awarded amount provided that OMB cost principles requiring reasonable compensation are observed. In general, graduate student compensation will not be considered reasonable if in excess of the amount paid to a first-year postdoctoral scientist at the same institution performing comparable work.

2.3.7.10 NIH Genomic Data Sharing

NIH Genomic Data Sharing (GDS) Policy expects that applicants preparing grant applications state in the cover letter when the studies proposed will generate large-scale human and/or non-human genomic data. Applications proposing such research are expected to describe a genomic data sharing plan. Plans for sharing genomic data as expected by the GDS Policy in the Data Management and Sharing Plan submitted with the application, and not in separate GDS Plan or at Just-in-Time, consistent with the changes described in 8.2.3.1 Policy for Data Management and Sharing. Guidance on developing data sharing plans may be found on NIH's scientific data sharing website.

Applicants who wish to use controlled-access human genomic data from NIH-designated data repositories as a secondary user, to achieve the specific aim(s) of the research proposed in the Research Plan of the application, should briefly address their plans for requesting access to the data, and state their intention to abide by the NIH Genomic Data User Code of Conduct. NIH acknowledges that data sharing is not always possible. Exceptions to the data sharing expectation may be requested in cases where the criteria in the Institutional Certification cannot be met.

2.3.7.11 Human Fetal Tissue from elective abortions

For competing grant applications proposing the use of Human Fetal Tissue (HFT) from elective abortions NIH requires applicants to address HFT requirements by providing a justification of the use of

HFT, details regarding procurement and costs, and information about how the applicant will use HFT. These additional requirements can be found in the application instructions and must be met within existing applicable page limits.

Applications that do not address all of the required information, including the detailed budget, will be administratively withdrawn and not reviewed.

2.3.7.12 Biographical Sketches (Biosketches)

NIH requires submission of a biographical sketch (also referred to as biosketch) for each proposed senior/key personnel and other significant contributor.

Applicants and recipients are required to submit biosketches in 1) competing applications for all types of grant programs; 2) in progress reports when new senior/key personnel or other significant contributors are identified; and 3) to support prior approval requests for changes in senior/key personnel status and changes of recipient organization.

NIH staff and peer reviewers utilize the biosketch to ensure that individuals included on the applications are equipped with the skills, knowledge, and resources necessary to carry out the proposed research. Applications containing one or more biosketches that do not conform to the required format may be withdrawn.

See the NIH Biosketch page for format pages, instructions and the NIH disclosure table.

2.3.8 Application Forms

Exhibit 3 lists the required application forms for competing applications, which vary by support mechanism. These forms and associated instructions are available on the OER forms page.

Exhibit 3. Required Forms for Competing Applications

Application Title	Form Number	Use
SF424 (R&R) Application Guide for NIH and Other PHS Agencies	SF424 (R&R)	The SF424 (R&R) form set, combined with PHS 398 components, is used for electronic submission.
SF424 (R&R) Individual Fellowship Application Guide for NIH and AHRQ	SF424 (R&R) and PHS 416-1	The SF424 (R&R) form set, combined with a PHS Fellowship Supplemental form component, is used for electronic submission of individual fellowship applications. The Fellowship Supplemental form component is from the PHS 416-1.
Application for a Public Health Service Grant	PHS 398	Form PHS 398 is used for paper submission for those programs that have not yet transitioned to electronic submission.

The NIH competing applications now require electronic application submission. Questions about application forms and instructions may be directed to OPERA Systems Policy Branch, OER, NIH; see Part III for contact information.

2.3.9 Application Receipt Information and Deadlines

Applicants should carefully read instructions in the FOA and the application guide to determine submission requirements. The FOA will either provide unique application deadlines or refer to NIH's standard due dates.

NIH expects all applications to be submitted on time. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances and limited to two weeks past the due date. If an application is submitted late, a cover letter explaining the reasons for the delay must be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Only DRR, CSR has the authority to accept a late application; however, contacting DRR in advance will not influence the acceptance of a late application. The NIH policy on late applications is stated in the applicable application instructions. Also see 2.3.9.2 - Electronically Submitted Applications, below.

2.3.9.1 Paper Applications

Paper application submission dates fall under two different categories: 1) Standard Postmark/Submission Dates (also known as "send by" dates) and 2) Special Receipt Dates (also known as "arrive by" dates) which are specified in RFAs and PAs.

Applications submitted for the standard submission dates are considered on time if they are sent on or before the appropriate date listed and a proof of mailing is provided. The critical determination is when the application is sent, not when it arrives at NIH. Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark, or a dated receipt from a commercial carrier or the USPS. Private metered postmarks are not acceptable.

All paper applications must be submitted via either courier delivery or the USPS. The number of copies specified in the application instructions or announcement must be submitted to the central NIH receipt point for CSR noted in Part III.

Preaddressed mailing address labels are available on the applicable forms page on the OER web site.

Do not hand deliver your application to CSR. Applications delivered by individuals will not be accepted.

If the submission date falls on a weekend or a Federal holiday, the date for receipt/mailing is extended to the next business day.

A paper application submitted in response to an FOA with a unique receipt date (if one is specified in the FOA) must be received at NIH by the specified date. However, an application received after the deadline may be accepted if it carries a legible proof-of-mailing date assigned by the carrier not later than 1 week prior to the deadline date. This applies only to FOAs with specific, published receipt dates, i.e., dates other than the standard ones used for investigator-initiated applications. For FOAs using the standard submission dates, the policies described above for "send by" dates apply.

2.3.9.2 Electronically Submitted Applications

For applications submitted electronically for the Standard Due Dates, on time submission means the electronic grant application must be successfully submitted to Grants.gov on or before 5:00 p.m. local time (of the applicant institution / organization) on the appropriate date listed in the funding opportunity.

Applications submitted to FOAs with a single submission date are considered on time if they are submitted to Grants.gov on or before 5:00 p.m. local time (of the applicant institution / organization) on the appropriate date listed. Applications submitted for Special Receipt Dates are considered on time if they

are submitted to Grants.gov on or before 5 p.m. local time on the Grants.gov Closing Date. RFAs and PARs with special receipt dates always must be received by Grants.gov on the dates designated in the announcement.

If an application due date falls on a weekend, it will be extended to the following Monday; any time the date falls on a Federal holiday, the due date will be extended to the following business day. The application will be on time if it is submitted on or before the following business day.

There is a two week window of consideration after the application due date, during which time NIH might consider accepting a late application (see details below). When the application due date falls on a weekend or Federal holiday, and is extended to the next business day, the window of consideration for late submission of applications will be calculated from that business day. Acceptance of late applications will be made on a case-by-case basis, dependent upon the explanation provided in a cover letter submitted with the application.

NIH will not consider accepting late applications under the following circumstances:

- RFAs that must be reviewed on a compressed timeline and that have declared, in the Application Due Date field, “No late applications will be accepted for this Funding Opportunity Announcement”.
- Additional circumstances as outlined below:

Funding Opportunity Announcement Type		
PA*	PAR	RFA
2 week	2 week	2 week
		None if Application Due Dates Field States: "No late applications will be accepted for this Funding Opportunity Announcement".
*Includes PAS: Program Announcement with Set-Aside Funds		

NIH does not expect to accept any applications received beyond the window of consideration or for RFAs that specify no late applications will be accepted.

Please be aware that any reasons for late submission must be in relation to the individual(s) with the PD/PI role on the application. For multiple PD/PI (MPI) applications, the reasons may apply to any or all of the PD/PIs. This accommodation does not apply to co-Investigators, project leaders in a multi-component application, or other Key Persons listed in an application (unless they also have MPI status).

Examples of acceptable and unacceptable reasons for submission of a late application can be found in the NIH Policy for Late Application Submission.

The windows of time for consideration of late applications have been carefully chosen so that the late applications can be processed with the cohort of on-time applications.

Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH in advance will not influence the acceptance of a late application. Additional information on submission of electronic applications can be found in the applicable SF424 (R&R) Application Guide.

2.3.9.3 Modified Submission Policy for Appointed Members of NIH Review and Advisory Group and Reviewers with Recent Substantial Service

An alternative submission policy is available for certain applications submitted listing as PD/PI individuals serving as appointed members of NIH chartered standing study sections, NIH Boards of Scientific Counselors, NIH Advisory Boards or Councils, NIH Program Advisory Committees, and/or peer reviewers. Eligibility begins on the date the appointment becomes active and continues for six weeks after the official date of retirement from appointed committee service. Thus, if retirement from appointed service occurs on June 30, continuous submission is permitted until August 16 of that year. This policy applies to R01, R21, and R34 applications that would normally be received on standard application submission dates (not special receipt dates); and allows for applications to be submitted as soon as they are fully developed. The applications will be reviewed no later than 30 days before the corresponding Advisory Council. Applications using the multiple PD/PI model, are eligible if one or more of the PD/PIs are eligible for continuous submission. Continuous submission does not apply to applications for which the eligible members have roles other than PD/PI, including eligible members as sponsors for fellowships and mentors for career award applications.

See frequently asked questions.

2.3.9.4 Similar, Essentially Identical, or Identical Applications

Simultaneous submissions of identical applications to one or more components of the PHS are not allowed, and the NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization for the same receipt date. This includes derivative or multiple applications that propose to develop a single product, process or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical grant applications submitted by different applicant organizations will not be accepted for the same receipt date. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the principal investigator are the original work of the principal investigator and have not been used elsewhere in the preparation and submission of a similar grant application. Applications to the NIH are grouped by scientific discipline for review by individual Scientific Review Groups and not by disease or disease state. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed or the application(s) may not be reviewed.

Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.

2.3.9.5 Application Non-conformity

Applicants are reminded that non-conformity with application requirements can have serious consequences. NIH may withdraw any application identified during the receipt, referral and review process that does not conform with the instructions in the SF424 (R&R) Application Guide, the Funding Opportunity Announcement, and relevant NIH Guide Notices.

Some **examples** of how this policy is applied to NIH applications *include but are not limited to*:

- Applications containing one or more biosketches that do not conform to the required format may be withdrawn.
- Applications that do not conform to the page limit requirements because inappropriate materials have been included in other parts of the application may be withdrawn.

- Applications submitted as new but containing elements of a resubmission or renewal application that do not conform with the resubmission policy and may be withdrawn.
- Applications submitted after 5 PM local (applicant organization) time on the application due date may be withdrawn.

It is important to remember that these are just examples, and that all requirements specified in the SF424 (R&R) Application Guide, the Funding Opportunity Announcement, and relevant NIH Guide Notices are to be followed. Questions about application requirements can be directed to NIH "Grants Info" or the Division of Receipt and Referral.

If an application is withdrawn because it does not conform to the application preparation and submission instructions, a letter will be placed in the eRA Commons Status page for that application.

2.3.10 Fraud, Waste and Abuse of NIH Grant Funds

Any individual who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to NIH grants or grant funds should consider contacting:

- Your institution's Office of Sponsored Research, Compliance Office, or other responsible office,
- The NIH CGMO listed in the NoA for the IC that funded the grant,
- The DGCO/OPERA/OER.

In addition, allegations of criminal offenses should be reported to the Department of Health and Human Services, OIG Hotline.

The OIG has authority within HHS to conduct criminal investigations. The HHS OIG maintains a post office box and a toll-free hotline for receiving information from individuals concerning fraud, waste, or abuse under HHS grants and cooperative agreements. The identity of the caller is kept confidential, and callers are not required to give their names. The address and telephone number of the OIG and the OIG hotline are included in Part III.

Further allegations of non-criminal misuse of grant funds, and recipient conflict of interest should be reported to the NIH OMA.

OMA provides a centralized management survey and review capability to promote program integrity, conducts appraisals of alleged incidents of waste, fraud, and abuse and has lead responsibility for cases received through the Office of Inspector General (OIG) Hotline that are referred to NIH for action. OMA has no authority to undertake criminal investigations. OMA refers all allegations of criminal offenses to the OIG for investigation. The address and telephone number for the OMA, DPI are included in Part III.

False statements involving falsified, fabricated, or plagiarized information identified during research misconduct proceedings should be reported to the NIH Extramural Research Integrity Officer.

Examples of fraud, waste, and abuse that should be reported include, but are not limited to, embezzlement, misuse, or misappropriation of grant funds or property, and false statements, whether by organizations or individuals. Other examples include theft of grant funds for personal use; using funds for non-grant-related purposes; theft of federally owned property or property acquired or leased under a grant; charging the Federal government for the services of "ghost" individuals; charging inflated building rental fees for a building owned by the recipient; submitting false financial reports; and submitting false financial data in bids submitted to the recipient (for eventual payment under the grant).

The Federal government may pursue administrative, civil, or criminal action under a variety of statutes relating to fraud and making false statement or claims. Part II includes administrative and other remedies

the Federal government may use if a recipient deliberately withholds information or submits fraudulent information or does not comply with applicable requirements. Even if a grant is not awarded, the applicant may be subject to penalties if the information contained in or submitted as part of an application, including its certifications and assurances, is found to be false, fictitious, or fraudulent.

The Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 et seq., provides for the administrative imposition by HHS of civil penalties and assessments against any person who knowingly makes false, fictitious, or fraudulent claims to the Federal government for money, including money representing grants, loans, or benefits. A civil penalty of not more than $5,500 may be assessed for each such claim. If a grant is awarded and payment is made on a false or fraudulent claim, an assessment of not more than twice the amount of the claim, up to $150,000, may be made in lieu of damages. Regulations established by HHS at 45 CFR Part 79 specify the review process for imposing civil penalties and assessments, including hearing and appeal rights.

The Criminal False Claims Act, 18 U.S.C. 287, and 18 U.S.C. 1001, provides for criminal prosecution of a person who knowingly makes or presents any false, fictitious, or fraudulent statements or representations or claims against the United States. Violations of these statutes carry a maximum sentence of 5 and 8 years imprisonment, respectively.

The Civil False Claims Act, 31 U.S.C. 3729(a), provides for imposition of penalties and damages by the United States, through civil litigation, against any person who knowingly makes a false or fraudulent claim for payment, makes or uses a false record or false statement to get a false claim paid or approved, or conspires to defraud the Federal government to get a false claim paid. A “claim” includes any request or demand for money or property made to the United States or to a contractor, recipient, or other recipient, if the Federal government provides or will reimburse any portion of the funds claimed. Civil penalties of $5,500 to $11,000 may be imposed for each false claim, plus damages of up to three times the amount of the damages the government sustains because of the violation, and the costs of any civil action brought to recover such penalties and damages.

NIH also may administratively recover misspent grant funds pursuant to the authorities contained in 2 CFR Part 200.

2.3.11 Availability and Confidentiality of Information

2.3.11.1 Availability of Information

Except for certain types of information that may be considered proprietary or private information that cannot be released, most grant-related information submitted to NIH by the applicant or recipient in the application or in the post-award phase is considered public information and, once an award is made, is subject to possible release to individuals or organizations outside NIH. The statutes and policies that require this information to be made public are intended to foster an open system of government and accountability for governmental programs and expenditures and, in the case of research, to provide information about federally funded activities.

NIH routinely places information about awarded grants, including project title, the name of the PD/PI, and the project description, on the RePORT Web site. For funded research grant applications, NIH also sends the project description provided by an applicant to the DoC’s NTIS. NTIS disseminates scientific information for classification and program analysis. The public may obtain the project descriptions from RePORT or request them from NTIS. Other information may be released case by case as described in this subsection.

Several policies require acknowledgment of support and a disclaimer for publications, inventions, and other research products, as provided in Administrative Requirements—Availability of Research Results:

Publications, Intellectual Property Rights, and Sharing Research Resources and elsewhere in the NIHGPS.

2.3.11.2 Confidentiality of Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets, information that is commercial or financial, or information that is privileged or confidential, the pages containing that information should be identified as specified in the application instructions.

When such information is included in the application, it is furnished to the Federal government in confidence, with the understanding that the information will be used or disclosed only for evaluation of the application. The information contained in an application will be protected by NIH from unauthorized disclosure, consistent with the need for peer review of the application (including the agreement by peer reviewers and Advisory Council members to the NIH confidentiality and nondisclosure rules); and the requirements of the FOIA and Privacy Act (5 U.S.C. 552 as discussed below). However, if a grant is awarded as a result of or in connection with an application, the Federal government has the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Federal government's right to use the information if it is obtained without restriction from another source.

2.3.11.2.1 Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a (as amended), and its implementing regulations (45 CFR Part 5b) provide certain safeguards for information about individuals maintained in a system of records (i.e., information may be retrieved by the individual's name or other identifying information). These safeguards include the rights of individuals to know what information about them is maintained in Federal agencies' files (hard copy or electronic) and how it is used, how they may obtain access to their records, and how to correct, amend, or request deletion of information in their records that is factually incorrect.

The NIH maintains application and grant records as part of a system of records as defined by the Privacy Act: NIH 09-25-0225.

This system of record provides guidance on requirements for the management of applicable grant records in NIH's possession and include appropriate routine uses of such information. It also includes requirements for safeguarding the records and for record retention and disposal.

Parties other than PD/PIs may request the release of Privacy Act grant records. Such requests are processed under FOIA. For example, information requested by co-investigators in grant applications is released to them only when required under FOIA because they have no right of access under the Privacy Act. When releasing information about an individual to a party other than the subject of the file, NIH will balance the individual's right to privacy with the public's right to know as provided by the FOIA.

Records maintained by recipients ordinarily are not subject to the requirements of 45 CFR Part 5b.

2.3.11.2.2 The Freedom of Information Act

The Freedom of Information Act, 5 U.S.C. 552, and implementing HHS regulations (45 CFR Part 5) require NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information. These policies and regulations apply to information in the possession of NIH. Generally NIH cannot require recipients or contractors under grants to permit public access to their records. An exception related to certain research data is described in this subsection.

NIH generally will release the following types of records pursuant to a FOIA request:

- Funded applications and funded progress reports, including award data.
- Final reports that have been transmitted to the recipient organization of any audit, survey, review, or evaluation of recipient performance.

NIH generally will withhold the following types of records or information in response to a FOIA request:

- Pending competing grant applications
- Unfunded new, renewal, and revision applications
- Financial information pertaining to project personnel, such as institutional base salary information
- Information pertaining to an individual, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
- Predecisional opinions in interagency or intraagency memorandums or letters expressed by Federal government officers, employees, or consultants
- Evaluative portions of site visit reports and peer review summary statements, including impact scores
- Trade secrets and commercial, financial, and otherwise intrinsically valuable items of information that are obtained from a person or organization and are privileged or confidential
- Information which, if released, would adversely affect the competitive position of the person or organization
- Patent or other valuable commercial rights of the person or organization.

Applicants are instructed to identify proprietary information at the time of submission of an application. If, after receiving a FOIA request, NIH has substantial reason to believe that information in its records could reasonably be considered exempt from release, the appropriate NIH FOI office will notify the applicant or recipient, through the PD/PI, before the information is released. In the case of multiple PD/PI's the Contact PD/PI will be notified and is responsible for coordinating any response to the notice. Multiple responses to the notice will not be accepted. If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA. The PD/PI will be given five (5) working days to identify potentially patentable or commercially valuable information that the PD/PI believes should not be disclosed. Any such submission must be specific as to the nature and type of commercial harm that will result if the requested information is released. Submissions that merely state in general terms that the grant application or portions should not be released will not be honored. If the PD/PI does not respond within that time period, the grant will be prepared for release in accordance with applicable FOIA policies and released to the requester. If the PD/PI does identify commercial or proprietary information an NIH official will review that response. After NIH consideration of the response, the PD/PI and recipient will be informed if NIH does not agree with the PD/PI's position. If a document contains both disclosable and non-disclosable information, the non-disclosable information will be redacted and the balance of the document will be disclosed.

The HHS regulations implementing FOIA provide that only the NIH FOI Officer may deny requests for information. Requests for information, the release of which is believed to be exempt under FOIA, are referred to the NIH FOI Officer along with written documentation of the rationale for nondisclosure. If the NIH FOI Officer determines that the requested information is exempt from release under FOIA, the requester may appeal that determination to the Deputy Assistant Secretary for Public Affairs (Media), HHS. Additional information on the FOIA process is available at the NIH FOI Office Web site.

2.3.11.2.3 Access to Research Data

NIH handles requests for the release of research data by certain types of recipients as FOIA requests. The term "research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

As required by 2 CFR Part 200.315 and 45 CFR Part 75.322, recipients that are institutions of higher education, hospitals, or non-profit organizations must release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). If the data are publicly available, NIH directs the requester to the public source. Otherwise, the IC FOI coordinator handles the request, consulting with the affected recipient and the PD/PI. This requirement also provides for assessment of a reasonable fee to cover recipient costs and (separately) the NIH costs of responding.

This requirement to release research data does not apply to commercial organizations or to research data produced by State or local governments. However, if a State or local governmental recipient contracts with an IHE, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to the disclosure requirement.

Additional information is available on the NIH web site. (Also see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.)

2.3.12 Protecting Sensitive Data and Information Used in Research

Recipients of NIH funds are reminded of their vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known and is satisfactory to the transmitter. See also Public Policy Requirements and Objectives—Federal Information Security Management Act.

2.4 THE PEER REVIEW PROCESS

Competing applications for NIH grants and cooperative agreements, including renewals and revisions, are subject to peer review as required by sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006 and 21st Century Cures Act.. NIH policy is intended to ensure that applications for funding submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias. The peer review system used by NIH, often referred to as the "dual review system," is based on two sequential levels of review for each application—initial review by an IRG or SRG, and a second level of review by the IC National Advisory Council/Board.

The NIH peer review process has evolved over the years to accommodate increasingly collaborative and multi-disciplinary research, changes in workload, resource constraints, and recommendations of various groups that have studied it. However, the underlying basis for the system—to provide a fair and objective review process in the overall interest of science—has not changed. Information concerning NIH's peer review process may be found at NIH's web site or GrantsInfo.

2.4.1 Initial Review

2.4.1.1 Responsibilities

The DRR in the CSR is the receipt point for all competing grant applications submitted to NIH, whether the peer review will be conducted by CSR or by an IC. The primary determining factors in whether CSR or an IC will be responsible for the peer review are the announcement type, the support mechanism, and/or the program. In general, CSR is responsible for the initial review of research project grant applications (including AREA applications), Kirschstein-NRSA individual fellowship applications, and SBIR/STTR applications, while the ICs handle the initial review of applications that have Institute-specific features such as conference grant applications, applications resulting from RFAs, and program project and center grant applications. CSR also may review other types of applications at IC request.

When the IC is responsible for the initial review, CSR reviews the application for completeness and staff in the soliciting IC review the application for responsiveness to the RFA/PAR/PAS, if applicable, and the scientific review office in that IC coordinates the initial technical review, and prepares the summary statements.

CSR Referral Officers, who are senior health scientist administrators with both research and scientific review experience, assign each application to one or more ICs for potential funding and to an IRG or SRG for initial review of the scientific merit of the application. These determinations are made on the basis of the application's contents, the referral guidelines, and any written request by the applicant organization (accompanying the application) for a specific study section or IC assignment.

SRGs, including CSR study sections, are organized by scientific discipline or current research areas and are managed by health scientist administrators functioning as SROs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRO often adds temporary members or other additional reviewers. Ad hoc SEPs are formed to review applications that cannot be reviewed by a standing review group or study section because they require special expertise or involve other special circumstances.

SRGs, whether study sections or SEPs, are primarily composed of non-federal scientists who have expertise in relevant scientific disciplines and are actively engaged in research. NIH's conflict-of-interest and confidentiality of information requirements for reviewers are intended to promote an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Applicants are notified by e-mail that the application has been received and that they can find information about the SRO, SRG, and IC assignments for the application in the eRA Commons. At this time, applicants may request reconsideration of the SRG and IC assignment. Applicants also are notified by e-mail to check eRA Commons for any change in the application's SRG or IC assignment, as well as a change in Council date. Once the assignment process is completed, the SRO is the primary contact for communication with the applicant until the summary statement is released. An applicant organization may withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PD/PI and an AOR.

In preparation for the initial review, SROs review applications to determine whether they are complete and conform to administrative requirements. For each reviewable application, they then assign (from among the standing and temporary members) at least three reviewers to write a critique of the application, provide initial scores, and to be prepared to discuss the application in detail.

Following the initial review, the SRO prepares a summary statement for most applications reviewed. The summary statement includes the reviewers' written comments, and, for scored applications, a summary of the discussion, and an impact score. Summary statements are then provided to the IC's program staff, Advisory Councils, the PD(s)/PI(s), and applicant institution's Authorized Organization Representative.

2.4.1.2 Overall Impact

The SRG assesses overall impact in the determination of scientific and technical merit; overall impact is defined differently for different types of applications. When considering applications for research grants and cooperative agreements, reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five scored review criteria, and additional review criteria (as applicable for the project proposed). All of the criteria, weighted as appropriate for each application or as described in the FOA, will be considered when assigning the overall impact score.

2.4.1.3 Scored Review Criteria

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, and enhance health. For research grant applications, and most other types of applications, reviewers judge the overall impact to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, taking into account, among other pertinent factors: Significance, Investigator(s), Innovation, Approach, and Environment. These scored review criteria may not be applicable for some types of applications. When these criteria are not applicable, the FOA will include the specific review criteria.

Reviewers will consider each of the five criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

The FOA should be consulted for additional information describing each of the scored review criteria.

2.4.1.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- Diversity Plan (for Conference Grant Applications)
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan.
- Vertebrate Animals

- Resubmission Applications
- Renewal Applications
- Revision Applications
- Biohazards

The FOA should be consulted for additional information describing each of the relevant additional review criteria.

2.4.1.5 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- Provision of Family Care Facilities (for Conference Grant Applications)
- Applications from Foreign Organizations
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

The FOA should be consulted for additional information describing each of the relevant additional review considerations.

Although the review criteria are intended for use primarily with investigator-initiated research project grant applications (e.g., R01 and P01), including those in response to PAs, to the extent reasonable, the criteria also will form the basis of the review of solicited applications and research related activities. However, for some activities (e.g., construction grants), the use of these criteria may not be feasible. Applications also may be reviewed against other pertinent factors as stated in FOAs.

2.4.2 Appeals of Initial Scientific Review

To preserve and underscore the fairness of the NIH peer review process, NIH has established a peer review appeal system to provide applicants the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was procedurally flawed. The NIH policy for appeals of initial peer review does not apply to appeals of the technical evaluation of Research and Development contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT awards. In addition, NIH will not review a resubmission application when an appeal of initial peer review is pending on the original application. As stated in the funding opportunity announcement, appeals of initial peer review outcome will not be accepted for applications in response to an RFA.

An appeal is a written communication from a Program Director/Principal Investigator (PD/PI) and/or applicant institution that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw or perceived flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence from the Authorized Organization Representative (AOR).

An applicant who is concerned about procedural aspects related to the completed initial peer review of their application first should consider the comments in the summary statement, and then should contact

the appropriate NIH Program Official (PO). Following discussion of concerns with the PO, if the PD/PI and/or an official of the applicant organization wishes to appeal the outcome of the initial peer review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO. The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and AOR concurrence to the PO. A communication from the PD/PI or official of the applicant organization (other than the AOR) only or with a "cc" to the AOR will not be accepted. The PO will send the PD/PI and/or institutional official, and AOR, an acknowledgement letter within 10 days of receipt of the appeal letter.

An appeal letter will be accepted only if the letter 1) describes the flaws in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest, as specified in regulation at 42 CFR Part 52h.5 "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more non-Federal peer reviewers.
- Lack of appropriate expertise within the SRG.
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

If review staff and program staff do not support the appeal, or do not agree on its merit, the PD/PI and/or an institutional official (not necessarily the AOR) may elect to withdraw the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the request directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and their concurrence to the PO. A communication from the PD/PI or institutional official (other than the AOR) only or with a "cc" to the AOR will not be accepted.

If review staff and program staff do not support the appeal, or do not agree on its merit, and the appeal letter is not withdrawn, the appeal letter will be made available to Council. The IC may not deny the PD/PI or applicant organization the opportunity to have an appeal letter made available to Council. Only two outcomes are possible following consideration of an appeal letter by Council:

- The Council may concur with the appeal, and recommend that the application be re-reviewed.
- The Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. No action by the Council is equivalent to concurrence with the SRG's recommendation and denial of the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

The Executive Secretary for the Council will communicate the Council recommendation concerning an appeal to the PD/PI, AOR, and NIH staff with a need to know. If the appeal letter was received by the IC deadline, the PD/PI and AOR will receive a written explanation of the resolution no later than 30 calendar days after the Council meeting. If the appeal letter was received after the IC deadline, the Executive Secretary will provide, no more than 30 calendar days after the date when the appeal letter was received, a written explanation of the IC's plan for making the appeal available to Council.

If the Council recommended that the application be re-reviewed, the original application will be re-reviewed without additional materials or modifications. The application may be re-reviewed by the same or a different SRG, depending on the flaws in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. The outcome of the re-review is final and cannot be appealed again.

On occasion, and for specific circumstances, the NIH may suspend temporarily the policy and process for handling appeals of NIH initial peer review. Such decisions will be announced in NIH Guide Notices and/or the relevant Funding Opportunity Announcements when they are issued in the NIH Guide for Grants and Contracts.

2.4.3 National Advisory Council or Board Review

Summary statements for those applications recommended for further consideration are presented to the assigned IC National Advisory Council or Board (hereafter "Council") for use in the second level of review. Council members include senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission. The Council reviews applications not only for scientific and technical merit, as judged by the SRG, but also for relevance to the IC's programs and priorities. The Council may concur with the SRG's recommendation, may decide not to recommend an application on the basis of program or policy considerations, or may recommend deferral of an application and refer it back to the SRG for re-review.

In addition, Council members will receive a list of competing applications that will be considered for funding from PD/PIs that meet the threshold for Special Council Review. These are investigators who currently receive $2 million or more in total costs (inclusive of direct and indirect) per year of NIH funding to support Research Project Grants. Council members will be asked to recommend consideration of funding for applications that afford a unique opportunity to advance research which is both highly promising and distinct from the other funded projects from the PD/PI. This does not represent a cap to NIH funding.

With very limited exception, an application may not be considered for funding unless it has received a favorable recommendation by both the SRG and the Council. For some applications (e.g., Kirschstein NRSA Fellowship applications) the second level of review is conducted by senior level IC staff.

2.4.4 Disposition of Applications

All incomplete applications, non-compliant applications, and applications determined to be non-responsive to FOA requirements will not be reviewed. If the FOA remains open with subsequent submission dates, the applicant may resubmit a corrected or complete version of an investigator-initiated application for consideration in the next review cycle. One resubmission application may be submitted for an appropriate due date up to 37 months after the application due date of the initial application, provided the FOA allows resubmission applications. Any application on the same topic proposed as a resubmission more than 37 months from the initial receipt date will not be accepted; it must be formatted and submitted as a new application.

Following the initial review, the summary statement will be available to the PD/PI and Authorized Organization Representatives (AORs) of the applicant organization with the Signing Official (SO) user role in the eRA Commons. If an application does not result in funding, there may be an opportunity to respond to the reviewers' comments and resubmit the application, provided the FOA allows resubmission applications. Applicants just receiving their summary statements should consult the NIH Next Steps page for detailed guidance. Applicants seeking advice beyond that available online may want to contact the NIH Program Officer listed at the top of the summary statement.

The IC Director or designee is the official who has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit one revised version of the application for review in a future cycle.

Some of the ICs publish paylines as part of their funding strategies to guide applicants on their likelihood of receiving funding. Application scores can only be compared against the payline for the fiscal year when the application will be considered for funding, which is not necessarily the year when it was submitted. At the beginning of fiscal years when the agency awaits an actual budget, there may be a delay of several months to determine paylines. If the application is assigned to an IC that does not announce a payline, the Program Officer listed at the top of the summary statement may be able to provide guidance on the likelihood of funding.

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The process leading to an award, including the business management review performed by the GMO, is described in Completing the Pre-Award Process below.

For unsuccessful applicants, the NIH will send a centralized, automated correspondence to the applicant organizations to notify of NIH's intent not to fund the indicated applications.

The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any NIH or HHS official or board.

2.5 COMPLETING THE PRE-AWARD PROCESS

Following the peer review process, applications that an IC may fund are reviewed for a number of other considerations. These include, as applicable, alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements. The applicant may be asked to submit additional information (such as other support or verification of IACUC approval) or to undertake certain activities (such as negotiation of an F&A cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if specific award conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before NIH makes a new award, recipients must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support. The pre-award process for non-competing continuation awards is a streamlined version of this process, including an assessment of progress (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

2.5.1 Just-in-Time Procedures

NIH uses Just-in-Time procedures for certain programs and award mechanisms (each FOA will include specific guidance on the use). These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

Applicants will be notified (primarily by e-mail) when Just-in-Time information is needed. This notification is not a Notice of Award nor should it be construed to be an indicator of possible funding. Applicants should only submit this information when requested. Information must be submitted electronically using the Just-in-Time feature in the eRA Commons. In some circumstances the GMO may ask for information in addition to the descriptions below, e.g., if the application involves hESCs and the applicant did not identify a hESC from the NIH Registry in the application.

The requirement for applicants to verify the accuracy and validity of all administrative, fiscal, and programmatic information extends to information submitted through the Just-in-Time process. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award. This includes items such as Other Support changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any Senior/Key Personnel; or any changes in the use or approval of vertebrate animals or human subjects. Similar to the NIH public policy requirements, applicants are responsible for establishing and maintaining the necessary processes to monitor its compliance and informing NIH of any problems or concerns. Failure to address changes to Just-in-Time submissions prior to award does not diminish the applicant's responsibility to address changes post-award by submitting a prior approval request to NIH in accord with Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award.

Other Support. Information on other active and pending support will be requested as part of the Just-in-Time procedures. Other support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes:

- Resources and/or financial support from all foreign and domestic entities that are available to the researcher. This includes but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.). Institutional resources, such as core facilities or shared equipment that is made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources.
- Consulting agreements, when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities and the activities fall outside of their appointment at the applicant or recipient institution.
- In-kind contributions, e.g. office/laboratory space, equipment, supplies, or employees or students supported by an outside source. If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, the recipient must provide reasonable estimates.

Other support does not include training awards, prizes, or gifts. Gifts are resources provided where there is no expectation of anything (e.g. time, services, specific research activities, money, etc.) in return. An item or service given with the expectation of an associated time commitment is not a gift and is instead an in-kind contribution and must be reported as Other Support.

Reporting of other support is required for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Information on Other Support is not specifically requested for Program Directors, training faculty, and other individuals involved in the oversight of training grants since applicable information is collected in other sections of a training grant application. It is also not requested for individuals categorized as Other Significant Contributors.

Recipients are expected to establish and maintain effective internal controls (e.g. policies and procedures) to ensure that individuals designated in applications as senior/key personnel fully disclose all Other Support information to their institution as soon as it becomes known. When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the recipient must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

For Other Support submissions that include foreign activities and resources, recipients are required to submit copies of contracts, grants, or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution as supporting documentation. If they are not in English, recipients must provide translated copies.

The supporting documentation must be provided as part of the Other Support PDF following the Other Support Format page. See NIH Other Support page for forms, instructions, and other resources.

IC scientific program and grants management staff will review this information before award to ensure the following:

- Sufficient levels of effort are committed to the project.
- There is no scientific, budgetary, or commitment overlap.
    - Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.
    - Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.
    - Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application.
    - Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the IC with the applicant and the PD/PI at the time of award.
- Only funds necessary to the approved project are included in the award.
- Any foreign resources that meet the definition of a foreign component have received appropriate prior approval.

See NIH Other Support for format page, instructions and the NIH disclosure table.

Certification of IRB Approval. If the proposed project involves human subjects research, a certification to NIH that all non-exempt human subjects research has been reviewed and approved by an appropriate IRB must be submitted. Pending or expired approvals are not acceptable. See Public Policy Requirements/Human Subjects for additional information.

Verification of IACUC Approval. If the proposed project involves research with live vertebrate animals, verification of the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable. See Public Policy Requirements/Animal Welfare for additional information.

Human Subjects Education Requirement. If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted. See Public Policy Requirements/Human Subjects/Education in the Protection of Human Research Participants for additional information.

Human Embryonic Stem Cells (hESCs). If the proposed project involves hESCs and the applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line (s) should be included in the Just-in-Time submission.

Genomic Data Sharing Institutional Certification. If the proposed project involves a Genomic Data Sharing plan. The certification form and directions for completing it are available on the GDS Data Sharing website: https://osp.od.nih.gov/scientific-sharing/institutional-certifications/. This certification should be submitted as an "other Upload" in the eRA Commons Just-in-Time module.

SBIR Funding Agreement Certification. For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification described in Section 2.18 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://-grants.nih.gov/grants/forms/manage_a_small_business_award.htm. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

STTR Funding Agreement Certification. For STTR applicants, provide only upon request the STTR Funding Agreement Certification described in Section 2.19 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://-grants.nih.gov/grants/forms/manage_a_small_business_award.htm. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

My Bibliography Report of Publications. For renewal applicants to research training programs, a My Bibliography report of publications arising from work conducted by trainees while supported by the training grant will be requested as Just-in-Time information prior to award. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

Other Information Requested by the Awarding IC. NIH IC's may also request additional Just-in-Time information on a case-by-case basis, such as revised budgets or changes to the human subjects or vertebrate animal sections of the application. These changes should be submitted as an "Other Upload" file in the eRA Commons Just-In-Time module.

2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement

When requested by NIH as part of the pre-award process, PD/PIs and the AOR should discuss potential changes in scope with NIH PO and revise the Project Summary/Abstract, Specific Aims, and/or Public

Health Relevance sections of their application as appropriate. Once all issues are resolved, applicants should e-mail a document with final versions of the revised sections to the IC-designated e-mail address (normally a Program Official, Grants Management Official, or centralized e-mail box) as a single Microsoft Word or PDF file. Be reminded that all revised application information submitted to the NIH must be approved by an AOR. Applicants should use this template. The template includes specific headings that must be used for each section. All three headings must be included in the document that is submitted even if a particular section had no changes from the previous submission. If there are no changes for a section include the header but leave the text area blank to ensure appropriate processing of this information by NIH's electronic systems.

2.5.3 Determining Applicant Organization Eligibility

All applicant organizations must complete the one-time eRA Commons registration process prior to submitting any application (paper or electronic) to the NIH. During the registration process, NIH may make a preliminary assessment of applicant organization eligibility. In an effort to streamline the registration requirements and reduce the administrative burden (i.e., time between registration submission and NIH's final determination), NIH urges potential applicants to consider the following eligibility considerations:

- What is the nature of the research and business that your organization performs and how does that fit within the NIH mission?
- Is your organization professionally responsible for the research?
- How many people are in your organization?
- Are the researchers employed by your organization?
- Where physically is the proposed research to be conducted?
- Can you identify a Funding Opportunity Announcement that you would apply for?
- Has your organization applied to and/or been directly funded by any Federal agency?

Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH reserves the right to deny registration if an organization is determined not to be an appropriate applicant for a particular FOA. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

NIH awards may be made only to eligible applicants. Continued funding is dependent on the recipient's continued eligibility. In general, domestic or foreign, public or private, non-profit or commercial organizations and individuals are eligible to receive NIH grants. However, on the basis of statutory, regulatory, or published policy limitations, under certain programs or types of awards, NIH may limit eligibility to, or exclude from eligibility, classes or types of entities. Examples are limitations on the participation of foreign entities, and programs under which only small businesses are eligible applicants. The determination of eligibility includes verification of the applicant's status. The applicant may be required to provide proof of its status by submitting documentation; otherwise the AOR's signature on the application certifies that the applicant is eligible to apply for and receive an award (e.g., a small business applying under the SBIR or STTR programs).

In addition to reviewing organizational eligibility, NIH may consider other factors relating to the applicant's ability to responsibly handle and account for Federal funds and to carry out the project. These factors include the applicant's intended role in the project, the location where the project will be performed, the role of the PD/PI in the project, and the PD/PI's employment and citizenship status.

Although some of these same considerations are reviewed as part of the peer review, NIH's concern at this stage in the process is making an award to a legal entity that will be accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. NIH will not make an award to an applicant that does not have a substantive role in the project and would simply serve as a conduit for another entity.

2.5.4 Determining Eligibility of Individuals

It is the responsibility of the applicant organization to select the individuals who have the appropriate expertise to manage the scientific and administrative aspects of the project. The eligibility of these individuals to complete the project will be evaluated during peer review and at the IC level by grants management and program staff.

The GMO will verify whether the proposed PD/PI or other senior/key personnel are debarred or suspended from participation in Federal assistance programs (see Public Policy Requirements and Objectives—Debarment and Suspension for certification requirements).

Generally, PD/PIs and other personnel supported by NIH research grants are not required to hold any particular education degree, and are not required to be U.S. citizens. However, some NIH programs/mechanisms have a citizenship requirement. Any citizenship requirement will be stated in the FOA. In these cases, individuals are required to have the appropriate citizenship status when the award is made rather than when the application is submitted. For example, under most career development awards or Kirschstein-NRSA individual fellowships, the individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence at the time of award.

NIH requires the applicant to determine that individuals' visas will allow them to remain in this country long enough for them to be productive on the research project, but NIH does not provide guidance on or assess the different types of visas. NIH expects recipient organizations to have policies, consistently applied regardless of the source of funds, to address this area. If a grant is awarded and an individual's visa will not allow a long enough stay to be productive on the project, NIH may terminate the grant (see Administrative Requirements—Changes in Project and Budget and Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support).

The eligibility requirements for trainees and additional eligibility requirements for fellows are addressed in Ruth L. Kirschstein National Research Service Awards chapter in IIB.

In the post-award phase, NIH monitors changes in recipient and project status to ensure they meet legal and programmatic requirements and takes actions necessary to protect the Federal government's interests.

2.5.5 Cost Analysis and Assessment of Management Systems

The GMO will ensure that a cost analysis is performed on any application that requires a detailed budget. Cost analysis involves obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining data to determine the necessity for, and the reasonableness and allowability of, the costs included in the application budget. The extent of cost analysis will depend on the type of funding instrument and award mechanism, the complexity of the project, prior experience with the applicant, and other factors. Information on the applicable cost principles and on allowable and unallowable costs under NIH grants is provided in the Cost Considerations chapter.

The amount of NIH funding is based on reasonable and allowable costs consistent with the principles of sound cost management, considering IC priorities (e.g., program relevance), constraints on the growth of average grant costs, and available funds.

In addition to considering the specific information provided in the application, the GMO determines the adequacy of the applicant's financial and business management systems that will support the expenditure of and accountability for NIH funds. When an applicant has had no prior Federal grants or cost-reimbursement contracts, the GMO may review the applicant's financial management and other management systems before award, or within a reasonable time after award, to determine their adequacy and acceptability. For an applicant with prior NIH or other Federal cost-reimbursement awards, the GMO may review recent audit reports and other available information to determine whether the applicant's management systems meet thestandards established in 2 CFR Part 200. The GMO will advise the applicant if additional information is required. On the basis of the review results, the GMO will determine the need for any corrective action and may impose specific award conditions on the award.

PART II: TERMS AND CONDITIONS OF NIH GRANT AWARDS

Subpart A: General

3 OVERVIEW OF TERMS AND CONDITIONS

Part II includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards. Subpart A (IIA) includes those terms and conditions that apply, in general, to NIH awards. Subpart B (IIB) either expands on IIA coverage or specifies additional or alternate terms and conditions for particular types of awards, recipients, or activities.

These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

NIH recipients are responsible for complying with all requirements of the Federal award. NIH grants awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in the NoA.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts. This also includes any recent legislation.
- 2 CFR Part 200.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIHGPS generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the GMO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIHGPS apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the NIHGPS.

This NIHGPS is an aid to the interpretation of statutory and regulatory requirements. These terms and conditions are intended to be compliant with governing statutes and the requirements of 2 CFR Part 200, as modified by previously approved waivers and deviations. However, in the case of a conflict, the statutes and regulations govern.

If there is a perceived conflict between or among these three categories of requirements—statutory and regulatory requirements, the terms and conditions in the NIHGPS, and award-specific terms and conditions—or if the recipient has other questions concerning award terms and conditions, the recipient

should request written clarification from the GMO. This may be done at any time; however, if the inclusion of the term or condition would cause the recipient not to accept the award or to be unable to comply, the question should be raised before funds are requested from the HHS payment system. By drawing funds from the HHS payment system, the recipient agrees to the terms and conditions of the award.

3.1 FEDERALWIDE STANDARD TERMS AND CONDITIONS FOR RESEARCH GRANTS

In order to create greater consistency in the administration of Federal research awards, all Federal research agencies now utilize a standard core set of administrative terms and conditions on research and research-related awards that are subject to 2 CFR Part 200, to the extent practicable. The core set of administrative requirements for participating Federal research agencies and other pertinent documents are posted on the National Science Foundation's web site. Recipients are encouraged to review the companion documents which include a Prior Approval Matrix, National Policy Requirement Matrix, Subaward Requirement Matrix, and Agency-Specific Requirements. NIH implementation of these Federalwide research terms and conditions is also known as the "NIH Standard Terms of Award".

See Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award for more details.

4 PUBLIC POLICY REQUIREMENTS, OBJECTIVES AND OTHER APPROPRIATION MANDATES

NIH grants are subject to requirements intended to ensure that recipient organizations handle their Federal awards responsibly. Recipients are required to adopt and enforce policies that minimize the opportunity for improper financial gain on the part of the organization, its employees, and organizations and individuals whom they may collaborate, and that limit the potential for research results to be tainted by possible financial or other gain. In addition, NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.

This chapter addresses public policy requirements, objectives, and other appropriation mandates applicable to NIH awards. The term "public policy" indicates that the requirement is based on social, economic, or other objectives or considerations that may be attached to the expenditure of Federal funds by recipients, subrecipients, and contractors, in general, or may relate to the expenditure of Federal funds for research or other specified activities.

In addition to cross-cutting requirements that some or all Federal agencies must apply to their grant programs, NIH recipients and subrecipients are subject to requirements contained in the HHS annual appropriations act that apply to the use of NIH grant funds, applicable provisions in other Federal agencies' appropriations acts, including Treasury, and other Federal statutes. Some of those requirements are included here in a separate section titled Appropriation Mandates since they have been included in the appropriations acts for several years with little or no change. Those requirements may be changed or other requirements may be added in the future.

The public policy requirements, objectives, and appropriation mandates listed in Exhibit 4 apply to all NIH awards with exceptions as noted.

4.1 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients. The public policy requirements specified in this section set many of those standards. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information. The signature of the AOR on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions. The policies, certifications and assurances listed in this section may or may not be applicable to the project, program, or type of applicant organization. Requirements / objectives are listed in alphabetical order.

As noted in this section, some requirements may necessitate the submission of a separate document (e.g., human subjects assurance, certification of IRB approval or institutional exemption, civil rights assurance). Applicants and recipients should take particular note of these requirements (for example, see specific sections on Human Subjects Protections and Civil Rights Protections), the absence or inadequacy of which may delay an award or render an applicant ineligible for award.

The recipient is responsible for: 1) establishing and maintaining the necessary processes to monitor its compliance and that of its employees, consortium participants, and contractors with these requirements; 2) taking appropriate action to meet the stated objectives; and, 3) informing NIH of any problems or concerns.

If a grant is awarded on the basis of false or misrepresented information, or if a recipient does not comply with these public policy requirements, NIH may take any necessary and appropriate action, including using any of the remedies described in Administrative Requirements—Enforcement Actions or other available legal remedies.

Exhibit 4 contains information to help the recipient determine what public policy requirements, objectives and appropriations mandates apply to its activities and whether a requirement should be included in a consortium agreement or a contract for routine goods or services under the grant (see Glossary in Part I for definitions). The exhibit distinguishes between these types of transactions under a grant and indicates (by "Y" for Yes or "NA" for Not Applicable) whether a given requirement normally would apply. However, even if the exhibit indicates that a requirement is not applicable that requirement potentially could be applicable in a specific situation, e.g., if a contract under a grant involves research activity. Therefore, this exhibit should be used as general guidance only. The recipient should consult the terms and conditions of its award and should contact the GMO if it has any question concerning the applicability of a particular public policy requirement or objective.

Exhibit 4 also indicates where, in the NIHGPS, the individual public policy requirements, objectives and appropriation mandates are covered in more detail. The recipient should also consult its attorney, as appropriate, regarding particular questions about the governing statute or regulation as applied to its specific circumstances. Other cited policies or documents may provide additional information.

In addition to the requirements addressed in this section, there are applicable NIH administrative requirements outlined in the Administrative Requirements chapter.

Some programs may have special requirements and are covered in IIB.

Exhibit 4. Public Policy Requirements, Objectives and Appropriation Mandates *

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Military Recruiting and ROTC Program Access to Institutions of Higher Education 4.1.19	Y	N	N
Seat Belt Use 4.1.28	Y	NA	NA
Labor Standards under Federally Assisted Construction 10.5.3	Y (Construction Grants and major A&R Contracts Exceeding $100,000)	NA	Y
Smoke-Free Workplace 4.1.29	Y	NA	NA
Drug-Free Workplace 4.1.7	Y	NA	NA

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Flood Disaster Protection Act of 1973 –- Flood Insurance 10.10.1	Y (Construction grants only)	NA	NA
National Environmental Policy Act of 1969 (including Public Disclosure) 4.1.20 and 10.10.1	Y	NA	NA
Intergovernmental Review of Federal Programs under EO 12372 10.10.1	Y (Construction grants only)	NA	NA
Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 10.10.1	Y	NA	NA
Standards of Conduct 4.1.30	Y	NA	NA
Federal Funding Accountability and Transparency Act (FFATA) 4.1.8 and 8.4.1.5.5	Y	NA If under $30,000	NA If under $30,000
President's Emergency Plan for AIDS Relief (PEPFAR Program 4.1.22	Y	Y	Y
Nondelinquency on Federal Debt 4.1.21	Y	Y	NA
National Historic Preservation Act of 1966 - Archaeological and Historic Preservation Act of 1974 10.10.1	Y (Construction Grants; any award involving major or minor A&R, or any work resulting in physical changes to real property)	Y	Y
Lead-Based Paint Poisoning Prevention Act 10.10.1	Y (Construction grants only)	Y	Y
Investigational New Drug Applications/Investigational Device Exceptions 4.1.16	Y	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Inclusion of Women/Minorities as Subjects in Clinical Research 4.1.15.8	Y	Y	NA
Metric System 4.1.18 and 10.10	Y	Y	Y
Lobbying (Appropriation Mandate) 4.2.6	Y	Y	Y
Limited English Proficiency 4.1.2.5	Y	Y	NA
Pro-Children Act of 1994 4.1.23	Y	Y	Y
Safe Drinking Water Act 10.10.1	Y (Construction grants only)	Y	Y
Salary Limitation/Cap (Appropriation Mandate) 4.2.10	Y	Y	NA
Restriction on Distribution of Sterile Needles (Appropriation Mandate) 4.2.9	Y	Y	Y
Select Agents (see Public Health Security & Bioterrorism Preparedness and Response Act) 4.1.24.1.1	Y	Y	Y
USA Patriot Act 4.1.33	Y	Y	Y
U.S. Flag Air Carriers 7.9.1	Y	Y	Y
Text Messaging While Driving 4.1.31	Y	Y	Y
Restriction on Abortions & Exceptions (Appropriation Mandates) 4.2.8 & 4.2.8.1	Y	Y	Y
Wild and Scenic Rivers Act of 1968 10.10.1	Y (Construction grants only)	Y	Y
Protection of Wetlands (EO 11990) 10.10.1	Y (Construction grants only)	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Promotion or Legalization of Controlled Substances (Appropriation Mandate) 4.2.7	Y	Y	Y
Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents) 4.1.24.1.1	Y	Y	Y
Research Misconduct 4.1.27	Y	Y	NA
Research Involving Recombinant or Synthetic Nucleic Acid Molecules (including Human Gene Transfer Research) 4.1.26	Y	Y	Y
Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees 4.1.25	Y	Y	NA
Inclusion of Individuals Across the Lifespan as Participants in Research 4.1.15.7	Y	Y	NA
Copeland Act, when required by statute 10.10.1	Y (Construction grants only)	Y	Y
Controlled Substances 4.1.5	Y	Y	Y
Conservation of Petroleum and Natural Gas (EO 12185) 10.10.1	Y (Construction grants only)	Y	Y
Data and Safety Monitoring 4.1.15.6	Y	Y	Y
Dual Use Research of Concern 4.1.24.2	Y	Y	Y
Dissemination of False or Deliberately Misleading Information (Appropriation Mandate) 4.2.3	Y	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Davis-Bacon Act, when required by statute 10.10.1	Y (Construction grants only)	Y	Y
Confidentiality of Alcohol and Drug Abuse Patient/Client Records 4.1.4.2	Y	Y	Y
Architectural Barriers Act of 1968 10.10	Y (Construction grants and any grant involving major A&R)	Y	Y
Animal Welfare 4.1.1	Y	Y	Y
Acknowledgment of Federal Funding (Appropriation Mandate) 4.2.1	Y	Y	NA
Certificates of Confidentiality 4.1.4.1	Y	Y	Y
Coastal Zone Management Act of 1972 10.10	Y (Construction grants only)	Y	Y
Clinical Trials.gov 4.1.3	Y	Y	NA
Clean Air and Clean Water Act 10.10.1	Y (Construction grants only); for contracts exceeding $100,000	Y	Y
Earthquake Hazards Reduction Act of 1977 and Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (EO 12699) 10.10	Y (Construction grants only)	Y	NA
Human Subjects Protections 4.1.15	Y	Y	Y
Gun Control 4.2.4	Y	Y	Y
Fly America Act 4.1.11	Y	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Hotel and Motel Fire Safety Act of 1990 14.6.1	Y (Conference Grants Only)	Y	Y
Human Fetal Tissue Research (Including Transplantation Research) 4.1.14	Y	Y	Y
Human Stem Cell Research 4.1.13	Y	Y	Y
Human Embryo Research and Cloning Ban (Appropriation Mandate) 4.2.5	Y	Y	Y
Health and Safety Regulations and Guidelines 4.1.12	Y	Y	Y
Endangered Species Act of 1973 10.10.1	Y (Construction grants only)	Y	Y
Equal Employment Opportunity 10.5	Y (Construction grants and any grant involving major A&R)	Y	NA If under $10,000
Financial Conflict of Interest 4.1.10	Y (NA to Phase I of the SBIR/STTR programs and to Federal institutions)	Y	NA
Federal Information System Security Management Act 4.1.9	Y	Y	Y
Age Discrimination Act of 1975 4.1.2.4	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Civil Rights Act of 1964 (Title VI) 4.1.2.1	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Health Insurance Portability and Accountability Act (HIPAA) 4.1.4.3	Y (if a covered entity)	Y (if a covered entity)	Y (if a covered entity)
Debarment and Suspension 4.1.6	Y (NA to certain foreign organizations)	Y (NA to certain foreign organizations)	Y If contract equals or exceeds $25,000 (NA to certain foreign organizations)
Education Amendments of 1972 (Title IX) 4.1.2.2	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Rehabilitation Act of 1973 (section 504) 4.1.2.3 and 10.10.1	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Lobbying (Federalwide Certification) 4.1.17	Y Certification required if total costs expected to exceed $100,000	Y Certification required if greater than $100,000 only	Y Certification required on contracts greater than $100,000 only
Trafficking in Persons 4.1.32	Y Private entities	Y Private entities	NA
Never Contract with the Enemy 4.1.36	Y	Y	Y
Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment 4.1.37	Y	Y	Y

* NA: A designation of NA in this table indicates that a particular requirement does not apply to an otherwise eligible recipient, consortium participant, or contractor or may not apply because the type of activity covered is one not normally performed by such an entity.

Please note that the core set of National Policy Requirements for participating Federal research agencies is maintained by the National Science Foundation and is posted here.

4.1.1 Animal Welfare Requirements

The *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all recipient organizations receiving PHS support for research or related activities using live vertebrate animals. Recipient organizations must establish appropriate policies and procedures to ensure the humane care and use of animals, and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

The PHS Policy incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495).

The PHS Policy defines “animal” as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or related purposes.

Applications from organizations proposing the use of animals are incomplete if they do not thoroughly address the use of vertebrate animals required in the Research Plan of the application. If the involvement of animals is indefinite at the time of application, the applicant should provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to conducting any animal activities the recipient must submit to the NIH awarding IC for prior approval the detailed information about the use of animals as required in the Research Plan of the application, and meet the Assurance and IACUC approval requirements of the PHS Policy.

Noncompeting and competing awards are prohibited from using NIH funds to procure cats from USDA Class B dealers. The procurement of cats may only be from USDA Class A dealers or other approved legal sources.

NIH funds may not be used to procure or support the use of dogs from Class B dealers. Dogs used in NIH-supported research may only be from USDA Class A dealers or other approved legal sources. Any costs incurred in violation of this policy are unallowable and will be subject to a cost disallowance.

No costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and IACUC approval of the activity.

The PHS Policy does not supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research. All recipient organizations are required to comply, as applicable, with the regulations (9 CFR, Subpart A) issued by the U.S. Department of Agriculture under the Animal Welfare Act, as amended, 7 U.S.C. 2131 et seq., and other Federal statutes and regulations relating to animals.

4.1.1.1 Animal Welfare Assurance Requirements

An Animal Welfare Assurance is the document submitted by an institution assuring institutional compliance with the PHS Policy. OLAW is responsible for requesting, negotiating, approving or disapproving, and, as necessary, restricting or withdrawing approval of Assurances.

When an applicant institution does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the institution will submit an Assurance when requested by OLAW. Upon such request, the institution shall prepare the Assurance as instructed by OLAW and in accordance with the PHS Policy, and the authorized IACUC shall review

those components of the application related to the care and use of animals. Except in certain circumstances, the Assurance must be submitted to and approved by OLAW in order for the IC to award the grant. No costs for activities with live vertebrate animals may be charged to NIH grants in the absence of a valid Assurance on file with OLAW.

If the prime recipient does not have an Assurance and the animal activities will be conducted at an Assured institution named as a performance site, the recipient must obtain an Inter-institutional Assurance from OLAW. Under the Inter-institutional Assurance, the recipient and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance.

4.1.1.2 Verification of IACUC Approval

NIH will delay an award for research involving live vertebrate animals until the recipient organization and all performance sites are operating in accordance with approved Animal Welfare Assurances and the recipient has provided verification of IACUC approval of those sections of the application that involve use of vertebrate animals. IACUC approval must have been granted within three years of the budget period start date to be valid; however, IACUCs may determine that continuing review on a more frequent basis is appropriate.

Verification of IACUC approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with approved Assurances may wish to proceed with IACUC review for those applications that have not yet received IACUC approval and that appear to be in a fundable range.

It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.

No costs for activities with live vertebrate animals may be charged to NIH grants if there is not a valid IACUC approval.

4.1.1.3 Consortiums

Under consortium (subaward) agreements in which the recipient collaborates with one or more other organizations, the recipient, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the recipient as specified in the NIHGPS (see Consortium Agreements chapter in IIB). The animal welfare requirements that apply to recipients also apply to consortium participants and subprojects.

The primary recipient is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. The approval of more than one IACUC is not required if the recipient and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted.

The recipient is further responsible for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).

The list of organizations with approved assurances is available at The OLAW web site posts a list of domestic institutions and foreign institutions with approved assurances.

4.1.1.4 Foreign Recipients and Foreign Performance Sites

Foreign recipients must provide OLAW with an Animal Welfare Assurance for Foreign Institutions. This constitutes institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the International Guiding Principles for Biomedical Research Involving Animals. IACUC approval is not required of foreign recipients; however, OLAW encourages foreign recipients to use the standards in the *Guide for the Care and Use of Laboratory Animals*.

When the recipient is a domestic institution and performance sites are foreign (i.e., domestic grant with a foreign component), PHS Policy requirements are applicable. Accordingly, the recipient remains responsible for animal activities conducted at the foreign site and must provide verification of IACUC approval (i.e., certification that the activities as conducted at the foreign performance site are acceptable to the recipient). The recipient IACUC may accept, as its own, the approval of a foreign organization's IACUC; however, the recipient IACUC remains responsible for the review. Additionally, the foreign site must obtain an Animal Welfare Assurance for Foreign Institutions as described in the preceding paragraph.

4.1.1.5 Reporting to OLAW

Reporting requirements under the PHS Policy include an annual report to OLAW describing any change in the institution's program for animal care and use as described in the Assurance, changes in IACUC membership, and the dates the IACUC conducted its semiannual evaluations of the institution's program and facilities. The IACUC, through the institutional official signing the Assurance, must promptly report any serious or continuing noncompliance with the PHS Policy, serious deviations from the Guide for the Care and Use of Laboratory Animals, and any IACUC suspensions.

Charges to NIH grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the grant award are not upheld are not allowable. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.
2. The conduct of animal activities in the absence of a valid IACUC approval of the activities. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

Instances of serious noncompliance with section IV.F.3. of the PHS Policy, such as those mentioned above, are to be reported to OLAW and the IC supporting the grant award. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. NIH requires that reports contain a certification that no unallowable costs were charged to NIH grant funds during a period of noncompliance. If such a certification cannot be made, a detailed accounting of unallowable charges made to each affected grant should be included with the report. If a detailed accounting has not been completed at the time of reporting, a date when it will be provided should be included.

NIH expects recipients to continue to maintain and care for animals during periods when animal activities are conducted in the absence of a valid Animal Welfare Assurance and/or IACUC approval. ICs may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis. Consultation with the IC is encouraged regarding questions concerning allowable costs.

Information about the PHS Policy, Animal Welfare Assurances, and other relevant topics is available from OLAW here.

4.1.2 Civil Rights Protections

Before NIH may make an award to a domestic organization, the AOR must certify, by means of the signature on the application, that the organization has on file with the HHS OCR a one-time Assurance of Compliance with the statutes described in this subsection. The Assurance, Form HHS 690, is filed for the organization and is not required for each application. If the application has been recommended for funding and the applicant organization does not have an Assurance of Compliance on file, it will receive the required form and instructions for completion and submission from the awarding IC. The HHS 690 also is available from GrantsInfo@nih.gov or by telephone at 301-435-0714.

Domestic organizations that receive funding from recipients (including consortium participants and contractors under grants) rather than directly from NIH, also are required to file an HHS 690. The applicant/recipient is responsible for determining whether those organizations have the required Assurance on file and, if not, ensuring that it is filed with OCR. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity, The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html

4.1.2.1 Civil Rights Act of 1964

Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 80.

4.1.2.2 Educational Amendments of 1972

Title IX of the Education Amendments of 1972 provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any educational program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 86.

4.1.2.3 Rehabilitation Act of 1973

Section 504 of the Rehabilitation Act of 1973, as amended, provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the physical or mental impairment, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. These requirements pertain to the provision of benefits or services as well as to employment. The HHS implementing regulations are codified at 45 CFR Parts 84 and 85.

4.1.2.4 Age Discrimination Act of 1975

The Age Discrimination Act of 1975 prohibits discrimination on the basis of age in any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 91.

4.1.2.5 Limited English Proficiency

EO 13166, August 11, 2000, requires recipients receiving Federal financial assistance to take steps to ensure that people with limited English proficiency can meaningfully access health and social services. A

program of language assistance should provide for effective communication between the service provider and the person with limited English proficiency to facilitate participation in, and meaningful access to, services. The obligations of recipients are explained on the OCR web site.

4.1.3 Clinical Trials Registration and Reporting in ClinicalTrials.gov Requirement

4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

For grant applications that request support for the conduct of a clinical trial, the NIH Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded recipients and investigators conducting clinical trials, funded in whole or in part by NIH, will ensure that their clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting. The purpose of the policy is to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Disseminating this information supports NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health. For basic experimental studies with humans (BESH) NIH continues to expect registration and results reporting, but with the additional flexibility to register and report results on alternative publicly available platforms. This flexibility only applicable to BESH studies submitted to funding opportunities designated as “basic experimental studies with humans” in the title and is available until September 24. 2023.

This policy is complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11, hereinafter referred to as the regulation.

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including applicable clinical trials subject to the regulation. All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov according to the timelines described in the regulation.

This policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Applicants seeking NIH funding for clinical trials will be required to submit a plan that will address how the expectations of this policy will be met. Recipients and investigators conducting clinical trials funded in whole or in part by NIH are required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.

The signature of the AOR on the grant or progress report form certifies that, for any clinical trials funded under the NIH award, the recipient and all investigators are in compliance with the recipient’s clinical trial information dissemination plan.

Responsibilities of recipients and investigators will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the recipient is the responsible party, the recipient will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the recipient is not the responsible party, the recipient will coordinate with the responsible party to ensure that all regulatory requirements are met.

3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the recipient will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Recipients of NIH funding conducting non-exempt human subjects research subject to the revised Common Rule and conducting a clinical trial as defined in 45 CFR Part 46.102(b) should be aware that for each funded trial, one IRB-approved consent form must be posted on a designated public federal website in accordance with 45 CFR Part 46.116(h). The forms must be posted on a designated public federal website after recruitment closes and no later than 60 days after the last study visit by any subject, as required by the protocol. More information about these requirements is available on the NIH web site.

- **NIH-funded recipients using an English-language informed consent form to enroll participants may either:**

Submit an IRB-approved English-language informed consent form to ClinicalTrials.gov. Documents that are uploaded to ClinicalTrials.gov should be uploaded in accordance with these instructions. ClinicalTrials.gov does not currently support upload of non-English documents. Or:

Submit an IRB-approved informed consent form to Regulations.gov following the instructions in the paragraph below. NIH recipients submitting informed consent forms to Regulations.gov must maintain a copy of their Regulations.gov receipt and tracking number, and make it available to NIH upon request.

- **NIH-funded recipients using only non-English informed consent forms to enroll participants:**

Submit an IRB-approved informed consent form to Docket ID: HHS-OPHS-2018-0021 on the Regulations.gov website in accordance with guidance issued by the Office for Human Research Protections. NIH recipients submitting informed consent forms to Regulations.gov must maintain a copy of their Regulations.gov receipt and tracking number, and make it available to NIH upon request.

Institutions submitting documents to either ClinicalTrials.gov or Regulations.gov must protect participant privacy in accordance with applicable federal, state, and local laws and regulations (e.g., the HIPAA Privacy Rule, Certificates of Confidentiality) and any applicable terms of their NIH award.

Each NIH-funded clinical trial should have only one entry in ClinicalTrials.gov that contains its registration and results information. Recipients need not and should not create a separate record of the applicable clinical trial to comply with this policy.

4.1.3.2 Food and Drug Administration Amendments Act (FDAAA)

Applicants and recipients should familiarize themselves with the requirements of 42 U.S.C. 282(j), also known as Sec. 801 of Public Law 110-85 (the FDA Amendments Act of 2007 or FDAAA), as implemented in regulation by 42 CFR Part 11, with respect to registration and results reporting requirements that apply to certain clinical trials. Of particular note is that, in general, results of applicable clinical trials are due not later than 12 months after the primary completion date. If this date occurs after the period of performance has ended, results reporting is still required in accordance with FDAAA and the terms and conditions of grant award.

The signature of the AOR on the grant or progress report form certifies that, for applicable clinical trials funded in whole or part by the award, the responsible party has made all registration and results submissions required by 42 CFR Part 11.

4.1.4 Confidentiality

4.1.4.1 Certificates of Confidentiality

In keeping with Section 301(d) of the PHS Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255, and as enacted December 13, 2016 Certificates of Confidentiality (Certificates) are issued automatically to any NIH funded investigators or institutions engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected.

At the time of enactment, all NIH-funded and conducted research that was commenced or ongoing on or after December 13, 2016 was deemed to be issued a Certificate and was therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act. Per the PHS Act, subsection 301(d)(1), the Certificates protect identifiable, sensitive information collected and all copies, in perpetuity.

Institutions and their investigators are responsible for determining whether research they conduct is subject to the requirement and therefore issued a Certificate. Certificates issued in this manner will not be issued as a separate document.

For the purposes of this Policy, NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR Part 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

Recipient Responsibilities

To determine if the requirement applies to research conducted or supported by NIH, investigators will need to ask, and answer the following question:

- Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer the following questions:

- Does the research involve Human Subjects as defined by 45 CFR Part 46?
- Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
- If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
- Does the research involve the generation of individual level, human genomic data?

If the answer to any one of these questions is yes, then the requirement will apply to the research and therefore, in accordance with subsection 301(d) of the Public Health Service Act, the recipient of the Certificate shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

As set forth in NIHGPS Chapter 8.3, recipients conducting NIH supported research applicable to the Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award.

Recipients of Certificates are required to ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate issued by the Policy, understand they are also subject to the requirements of subsection 301(d) of the Public Health Service Act. In accordance with NIHGPS Chapter 15.2.1, recipients are also responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sensitive information protected by a Certificate issued by the Policy understand they are also subject to subsection 301(d) of the Public Health Service Act.

For studies in which informed consent is sought, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by the Policy.

Information on CoCs is available on the NIH Web site at Certificates of Confidentiality (CoC) - Human Subjects.

4.1.4.2 Confidentiality of Alcohol and Substance Use Patient Records

Section 543 of the PHS Act, as implemented in 42 CFR Part 2, requires that records of substance abuse patients be kept confidential except under specific circumstances and purposes. These protections differ from those available to patients under HIPAA and are intended to ensure that a patient in a substance or alcohol use program is not made more vulnerable than a similar patient who does not seek treatment. The covered records are any information, written or not, of a patient who has applied for or been given diagnosis or treatment for substance or drug use at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an substance or drug user in order to determine that individual's eligibility to participate in a program. This includes records of the identity, diagnosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, training, treatment, rehabilitation, or research, which is conducted under an NIH grant. Except as authorized under a court order, no patient record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient. The regulations also describe procedures to allow for nonvoluntary disclosure of certain information by persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive substances.

4.1.4.3 Confidentiality of Patient Records: Health Insurance Portability and Accountability Act

HHS issued the final version of the "Standards for Privacy of Individually Identifiable Health Information"—the Privacy Rule—on August 14, 2002. The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information. It is administered and enforced by OCR, HHS.

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and the recipient organization. The OCR web site provides information on the Privacy Rule, including the complete text of the regulation and a set of decision tools for determining whether a particular entity is subject to the rule. An educational booklet, Protecting Heath Information in Research: Understanding the HIPAA Privacy Rule, is available through OCR's web site. That web site also includes other educational materials including information specific to grants.

4.1.5 Controlled Substances

If controlled substances are proposed to be administered as part of a research protocol or if research is to be conducted on the substances themselves, applicants/recipient must ensure that the DEA requirements, including registration, inspection, and certification, as applicable, are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC may be reached at 800-882-9539. Information also is available from the National Institute on Drug Abuse at 301-443-6300.

4.1.6 Debarment and Suspension

HHS regulations published in 2 CFR Part 376 implement the government-wide debarment and suspension system guidance (2 CFR Part 180) for HHS' non-procurement programs and activities. "Non-procurement transactions" include, among other things, grants, cooperative agreements, scholarships, fellowships, and loans. NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, recipients of NIH grants ("primary covered transactions"), including

sponsoring institutions for Kirschstein-NRSA individual fellowships, are required to determine whether it or any of its principals (as defined in 2 CFR Part 180.995 and 2 CFR Part 376.995) is excluded or disqualified from participating in a covered transaction (i.e., grant or cooperative agreement) prior to entering into the covered transaction, i.e., prior to the drawdown of funds which signals acceptance of the grant award. Recipients may decide the method and frequency by which this determination is made and may check excluded parties in SAM, although checking SAM is not required.

Prior to the drawdown of funds for each grant award, recipients must report to the funding IC if the recipient or any of its principals:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 CFR Part 180.800(a) or had a civil judgment for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses listed in 2 CFR Part 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years or default.

Disclosure of unfavorable information by recipients under this requirement will not necessarily cause NIH to deny participation in the grant. NIH will consider the information when determining whether to enter into the covered transaction. NIH will also consider any additional information or explanation that recipients elect to submit with the disclosed information. However, if it is later determined that a recipient failed to disclose information that it knew at the time it accepted the NIH grant award, NIH may (a) terminate the transaction for material failure to comply with the terms and conditions of the award or (b) pursue any other available remedies, including suspension and debarment.

Recipients must immediately report to the NIH funding IC if at any time during the project period, including periods of no-cost extension, they discover that they (a) failed to disclose information prior to the drawdown of funds or (b) due to changed circumstances the recipient or any of its principals for the grant now meet the reporting criteria.

“Lower tier” transactions (e.g., consortiums, subcontracts, consultants, collaborators, and contractors that require the provision of goods or services that will equal or exceed $25,000) also are subject to the HHS regulations. Prior to entering into a lower tier covered transaction with a participant (as defined in 2 CFR Part 180.980), recipients must verify that the person (as defined in 2 CFR Part 180.985) is not excluded or disqualified. Recipients may not enter into any transaction with a person who is disqualified from that transaction unless an exception under the disqualifying statue, Executive Order, or regulation has been obtained from HHS.

Recipients must require participants at the next lower tier to (a) comply with the HHS Debarment and Suspension regulations as a condition of participation in the transaction and (b) pass the requirement to comply with the HHS Debarment and Suspension regulations to each person involved in the covered transaction at the next lower tier. Likewise, before entering into such a transaction lower tier participants and contractors under grants (where the contract requires the provision of goods or services that will equal or exceed $25,000) must report to the recipient if it or any participants are presently excluded or disqualified.

Recipients also are required to assure compliance for each trainee under a Kirschstein-NRSA institutional research training grant, or other similar NIH-supported institutional training grant, before their appointment.

Organizations or individuals that are suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants, be paid from NIH grant funds, whether under a primary or lower-tier transaction (including trainees on NIH-supported training grants), or otherwise participate during the period of suspension, debarment, or exclusion. Because individuals who have been debarred, suspended, declared ineligible, or voluntarily excluded from covered transactions may not receive Federal funds for a specified period, charges made to NIH grants for such individuals (e.g., salary) are unallowable.

4.1.7 Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (41 U.S.C. § 701 et seq.) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the AOR agrees that the recipient will provide a drug-free workplace and will comply with the requirement to notify NIH if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. Government wide requirements for Drug-Free Workplace for Financial Assistance are found in 2 CFR Part 182; HHS implementing regulations are set forth in 2 CFR Part 382.400. All recipients of NIH grant funds must comply with the requirements in Subpart B (or Subpart C if the recipient is an individual) of Part 382. Foreign applicants and recipients may be exempted from the drug-free workplace requirements of 2 CFR Part 182 based on a documented finding by the NIH awarding IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government.

4.1.8 Federal Funding Accountability and Transparency Act (FFATA)

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible web site, USASpending.gov. The Web site includes information on each Federal financial assistance award and contract over $30,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including FAIN, transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and
6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: 1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on all subawards/subcontracts/consortiums over $30,000. Information on the recipient reporting requirement for this law can be found in Monitoring—Reporting—Financial Reports—Recipient Reporting of Subrecipient Data for FFATA.

Full text of the award term is available at 2 CFR Part 170.

4.1.9 Federal Information Security Management Act

All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access. This also applies to information associated with NIH grants and contracts. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of

federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), 44 U.S.C. 3541 et seq. The applicability of FISMA to NIH recipients applies only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. The recipient retains the original data and intellectual property, and is responsible for the security of this data, subject to all applicable laws protecting security, privacy, and research. If and when information collected by a recipient is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information and any derivative copies as required by FISMA.

4.1.10 Financial Conflict of Interest

NIH requires recipient institutions (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." (FCOI Regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements. FCOI requirements are aligned with 42 CFR Part 50--Subpart F and the overarching goal for reporting is to promote and encourage transparency in order to avoid distorting NIH funding decisions; NIH staff consider reports in light of other disclosures, e.g. other support, biographical sketch data, and foreign components, etc., and provide a holistic approach to award and risk management principles.

The requirements under the 2011 revised regulation promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants. These requirements do not apply to Federal employees or Federal agencies. Federal agencies have their own set of rules governing FCOI for employees. When submitting a grant application, the signature of the AOR certifies the applicant Institution's compliance with the requirements of the FCOI regulations, including that:

1. There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage FCOI with respect to all research projects for which NIH funding is sought or received;
2. The Institution shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests (SFI);
3. The Institution shall identify and manage FCOIs and provide initial and ongoing FCOI reports to NIH;
4. When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;
5. The Institution must fully comply with the requirements of the regulation.

When the Institution determines that an FCOI exists (see #3 above), the Institution must report to the NIH awarding IC through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module. The initial FCOI report will include the following information:

- Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model;
- Name of Investigator (if different from the PD/PI) with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
- Value of the financial interest $0-4,999; $5,000-9,999; $10,000-19,999; amounts between $20,000-100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000 or a statement that a value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan, including:
    1. Role and principal duties of the conflicted Investigator in the research project;
    2. Conditions of the management plan;
    3. How the management plan is designed to safeguard objectivity in the research project;
    4. Confirmation of the Investigator's agreement to the management plan;
    5. How the management plan will be monitored to ensure Investigator compliance; and
    6. Other information as needed.

The annual FCOI report must be submitted to NIH through the eRA Commons FCOI Module each year within a competitive segment or until the Institution reports that the FCOI no longer exists. The annual FCOI report will include the following information:

- Status of the FCOI
- Changes to the management plan, if applicable

The Institution will incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of the recipient Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the recipient Institution in sufficient time to allow the recipient Institution to report the FCOI to NIH to meet its reporting obligations. (See Consortium Agreements, 15.2.1 Written Agreement.)

The Institution will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible web site or by a written response to any requestor within five business days of a request and update such information as specified in the regulation.

Each Institution shall maintain an up-to-date, written, enforced policy on FCOI that complies with the regulation, and make the policy available via a publicly accessible web site. NIH funded recipients are required to submit their publicly accessible FCOI policy to NIH via the eRA Commons Institution Profile (IPF) Module (IPF Module). The information is provided on an institutional level as part of an institution's IPF, rather than on a grant-specific level, so it is not necessary to submit the FCOI policy with each grant application.

The Institution must require each Investigator to disclose their (and their spouse and dependent children) domestic and foreign SFIs that are related to their Institutional responsibilities to the Institution's designated official(s).

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education and foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000). Institutions are strongly encouraged to review their FCOI policy and make any necessary changes to ensure Investigators fully understand their disclosure responsibilities.

The Institution must require each Investigator (including subrecipient Investigators) to complete training prior to engaging in NIH-supported research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an Investigator noncompliant with the Institution's FCOI policy or management plan.

As described in the regulation, examples of how FCOIs might be managed include but are not limited to, the following:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- Disclosure of FCOI directly to human subjects research participants;
- Monitoring of research by independent reviewer(s);
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of SFIs (e.g., sale of an equity interest)
- Severance of relationships that create FCOIs.

The information above is only a sample of the regulatory requirements found in 42 CFR Part 50--Subpart F. Applicants and recipients must review the regulation in its entirety to ensure compliance with all of the requirements. Resources applicable to FCOI, including Frequently Asked Questions, etc. can be found on OER's Financial Conflict of Interest Web site. The NIH disclosure table can be found at https://grants.nih.gov/grants/forms/NIH-Disclosures-Table.pdf.

4.1.11 Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible. These circumstances are outlined below:

1. ***Airline "Open Skies" Agreement.*** A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union (EU). This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States.

   The U.S.-EU Open Skies Agreement was amended effective June 24, 2010. GSA issued Guidance October 6, 2010. Pursuant to the amendment, federal contractors and recipients (not U.S. Government employees) need not be concerned about city-pair contract fares. However, contractors and recipients must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically.

   Additionally, pursuant to the amendment, EU airlines are no longer limited to flying passengers between points in the United States and points in the EU. Instead, EU airlines are authorized to transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the U.S.-EU Open Skies Agreement. This includes flights that originate, arrive, or stop in the European Union. For additional information, please see the text of the Amendment and GSA Bulletin FTR 11-02. For information on other "open skies" agreements in which the United States has entered, refer to GSA's web site.

2. ***Involuntary Rerouting.*** Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service.
3. ***Travel To and From the U.S.*** Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
4. ***Travel Between Points Outside the U.S.*** Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
5. ***Short Distance Travel.*** For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

4.1.12 Health and Safety Regulations and Guidelines

Recipients are responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and

regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR Part 1910.1030, Blood borne pathogens; 29 CFR Part 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR Part 1910.
- Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available at https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf.
- Prudent Practices for Safety in Laboratories (2011), National Research Council, National Academies Press, 500 Fifth Street, NW, Lockbox 285, Washington, DC 20055 (ISBN 978-0-309-13864-2).

Recipient organizations are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines. However, if requested by the awarding IC, recipients should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.

4.1.13 Human Stem Cell Research

Under Executive Order 13505 NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. NIH Guidelines on Human Stem Cell Research, implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells.

For the purpose of NIH Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos.

NIH recipients may use hESCs that have been approved by NIH in accord with NIH Guidelines and are posted on the NIH Human Embryonic Stem Cell Registry, or may establish eligibility of specific cell lines for NIH funding by submitting a Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890). Prior to the use of NIH funds, applicants and recipients must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/recipient must provide a strong justification why one cannot be identified at that time and a certification that one from the NIH Registry will be used.

DHHS regulations for Protection of Human Subjects, 45 CFR Part 46, Subpart A, establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. When research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 CFR Part 46, Subpart A.

In addition, 45 CFR Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 CFR Part 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidance.

4.1.13.1 Human Pluripotent Stem Cell Research Prohibited with NIH Funding

The following uses of hESCs, even if derived from embryos donated in accordance with NIH Guidelines and listed on the NIH Registry, or human induced pluripotent stem cells, are prohibited:

- Research in which hESCs or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
- Research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line.

In addition, the derivation of stem cells from human embryos is prohibited in NIH funded research by the annual appropriations ban on funding of human embryo research known as the Dickey Wicker Amendment. NIH funding for research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is also prohibited.

NIH will not fund any new or competing grant applications for research in which human pluripotent cells are introduced into non-human vertebrate animal pre-gastrulation stage embryos.

- *Current research funding*: NIH will not consider requests for administrative supplements or revisions to any grants that include costs for or involve research introducing human pluripotent cells into non-human vertebrate animal pre-gastrulation stage embryos. Ongoing NIH awards will be addressed with the recipients on a case-by-case basis.
- *Peer reviewed competing applications*: Any grant applications previously submitted to NIH and already reviewed (through both the initial and Council levels of review) which propose to introduce human pluripotent cells into non-human vertebrate animal pre-gastrulation stage embryos will be held for funding decisions until NIH has issued a policy notification. At that time, highly ranked applications can be modified, as necessary, to comply with the policy notification to receive full consideration for funding.
- *Competing applications pending submission and/or peer review*: NIH will not review applications for research proposing to introduce human pluripotent cells into non-human vertebrate animal pre-gastrulation stage embryos until NIH has issued a policy notification.
- Once the policy notification is released, applicants for grants that have not completed initial peer review will have the opportunity to submit additional post-submission material to comply with the policy notification. Provided that the additional material can be sent 30 days before the initial peer review meeting, those grant applications will be reviewed and considered for funding. See instructions and details.

- Applications that completed initial peer review before issuance of this Notice will not proceed to Council review at this time.
- Alternatively, applicants may withdraw the application and submit again at the next available due date.

4.1.14 Human Fetal Tissue Research

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines.

Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects. 45 C.F.R. 46.204 and 46.206 may be specifically relevant.

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements. When an application involving human fetal tissue research is submitted to NIH, the AOR's signature certifies that researchers using these tissues are in compliance with the PHS Act. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term "valuable consideration" is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

Current federal laws and regulations require informed consent for research involving the transplantation of human fetal tissue and for research with human fetal material associated with information that can identify a living individual. Most states require informed consent for the use of fetal tissue in research. Accordingly, NIH expects informed consent to have been obtained from the donor for any NIH-funded research using human fetal tissue.

When obtaining primary human fetal tissue for research purposes, NIH expects recipients to maintain appropriate documentation.

4.1.14.1 Research on Transplantation of Human Fetal Tissue

Sections 498A and 498B contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:
    - for therapeutic transplantation research,
    - without any restriction regarding the identity of individuals who may receive the transplantation, and
    - without the donor knowing the identity of the recipient.

- The attending physician must sign a statement that they have:
    - obtained the tissue in accordance with the donor's signed statement and
    - fully disclosed to the donor their intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.
- In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that they:
    - obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
    - did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
    - performed the abortion in accordance with applicable State and local laws.
- The PD/PI must sign a statement certifying that they are aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.
- The PD/PI must certify in writing that they have had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the AOR that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

In addition, FDA has jurisdiction over fetal cells and tissues intended for use in humans and requests that investigators contact them to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available here.

4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions

For the purposes of this section, HFT from elective abortions is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following:

• human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.

• animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.

• derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.

• any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

- The definition of research involving HFT from elective abortions does not include the following:
    - human fetal primary or secondary cell cultures, if cells were not derived from an elective abortion
    - already-established (as of June 5, 2019) human fetal cell lines (e.g. induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines).
    - derivative products from human fetal tissue or cells (e.g. DNA, RNA, protein) if not derived from elective abortion.
    - human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi if not derived from elective abortion.
    - human fetal cells present in maternal blood or other maternal sources
    - human embryonic stem cells or human embryonic cell lines.
    - research on transplantation of HFT for therapeutic purposes (because of the statutory provision(s) addressing such research)."

NIH requires additional documentation of the use of HFT from elective abortions in research, as NIH does with other research materials and models, to ensure that it is utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes. NIH requires applicants to provide detailed information addressing the use of HFT in applications/proposals and reports. These requirements are designed to enable NIH to assess whether extramural research applicants and recipients are adequately assuring compliance with all applicable laws and HHS/NIH policies concerning the acquisition and use of HFT obtained from elective abortion.

NIH requires applicants to address HFT requirements by providing a justification of the use of HFT, details regarding procurement and costs, and information about how the applicant will use HFT. These additional requirements must be met within existing applicable page limits.

The addition of research involving HFT from elective abortions to a funded NIH grant project is considered an indicator of a change in scope and, due to the additional information required, such changes will require the submission of a competing revision application. Competing revision applications must include all required information, as described below. Administrative supplements to add HFT research will not be allowed. Complex grant mechanisms that include centers/cores with discretionary funds will not be allowed to expand existing HFT funding or to add HFT funded activities, including pilot projects.

Training awards and individual fellowships may not propose research using HFT. In addition, grant mechanisms that include centers with discretionary funds and Other Transaction Authority may not be used to support HFT research.

4.1.15 Human Subjects Protections

The HHS regulations for the protection of human subjects, in 45 CFR Part 46, implement Section 491(a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by NIH or other HHS components.

The HHS regulations state that institutions (whether domestic or foreign)that are engaged in nonexempt human subjects research and institutional boards (IRBs) reviewing research that is subject to the HHS regulations must comply with the regulations at 45 CFR 46 (Revised Common Rule §46.101(a) and Pre-2018 Common Rule §46.101(a)). Recipient institutions "engaged" in human subjects research must provide written assurance that it will comply with the regulatory requirements (Revised Common Rule §46.103(a) and Pre-2018 Common Rule §46.103(a)). The recipient institution provides written assurance by obtaining a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP) and establishing appropriate policies and procedures for the protection of human subjects (Revised Common Rule §46.108(a)(3) & (4) and Pre-2018 Common Rule §46.103(b) (4) & (5)). An institution is engaged in human subjects research if:

1. the institution's employees or agents intervene or interact with human subjects for research purposes;
2. the institution's employees or agents obtain individually identifiable private information or identifiable biospecimens about human subjects for research purposes; or
3. the institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

The OHRP's document entitled Guidance on Engagement of Institutions in Human Subjects Research provides additional guidance on "engagement".

The HHS regulations at Subparts B, C, and D include additional protections for specific populations as follows:

1. pregnant women, human fetuses and neonates (45 CFR Part 46, Subpart B);
2. prisoners (45 CFR Part 46, Subpart C); and
3. children (45 CFR Part 46, Subpart D).

Certain research activities are exempt from regulatory requirements for an FWA and IRB oversight (Revised Common Rule 46.104(d) and Pre-2018 Common Rule 46.101(b). OHRP guidance states that institutions must adopt clear procedures under which the IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations. NIH will review the materials submitted by the institution, including the PHS Human Subjects Clinical Trails Information Form of the application, to determine if it can concur with the institution that the proposed activities are covered by the regulations or are in one or more exempt category. For research potentially subject to an exemption, this includes reviewing which category of exemption applies. NIH's review does not relieve the institution of any of its regulatory responsibility to accurately make and implement correct determinations about the research for the entirety of the project or otherwise speak for regulatory entities within HHS.

Unless all research activities meet the criteria for one or more exemptions from 45 CFR Part 46, research involving human subjects may only be conducted under an HHS award if the organization has a current OHRP approved FWA and provides certification that an Institutional Review Board (IRB) registered with OHRP has reviewed and approved the proposed activity in accordance with the HHS regulations.

In accepting an award that supports human subjects research, the recipient institution assumes responsibility for all research conducted under the award, including protection of human subjects at all participating and consortium sites. The recipient institution also assumes responsibility for ensuring that all institutions under the award engaged in non-exempt human subjects research have a current, approved FWA and must obtain certification of approval by an IRB registered with OHRP, of all non-exempt human subjects research before human subjects research may begin. When consultants are performing

research involving human subjects on NIH-funded projects, the consultant's institution must obtain an FWA.

The NIH Office of Extramural Research Human Subjects web site contains additional information and Frequently Asked Questions that are available to help investigators understand how these Federal requirements apply to their research.

Applications will be considered incomplete if they do not address the involvement of human subjects in the PHS Human Subjects and Clinical Trials Information Form of the application. If human subjects research is anticipated within the period of the award but definite plans for involvement of human subjects cannot be described in the application (referred to as "delayed onset human subjects research" in the NIH grant application instructions), applicants must provide a detailed explanation of why it is not possible to develop definite plans. Prior to the involvement of human subjects the recipient must submit to the NIH awarding IC for prior approval either (1) detailed information as required in the PHS Human Subjects and Clinical Trials Information Form of the application, and meet the FWA and IRB certification requirements, or (2) if all of the research meets the criteria for one or more exemptions, identification of which exemptions(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate. Typically, recipients that are part of large clinical research networks or consortia that plan to add new protocols after the award must follow the awarding IC's procedures for approval of new protocols. Institutions with award mechanisms that allow them to select new projects, typically small future research projects (e.g., pilot projects), for support by their NIH award are responsible for ensuring that the selected projects follow all relevant regulations and policies including those governing the involvement of human subjects in research, including prior approval from the IRB if applicable. They must follow the awarding IC's procedures for prior approval of new protocols and updating the IC on the status of funded projects in annual progress reports which are typically described in the FOA and/or NoA.

Recipients may not draw funds from the payment system, request funds from the paying office, or make obligations against Federal funds for research involving human subjects at any site engaged in nonexempt research for any period not covered by both an FWA and IRB approval consistent with 45 CFR Part 46. Costs associated with IRB review of human research protocols are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.

The use of autopsy materials is governed by applicable State and local law and is not regulated by 45 CFR Part 46.

4.1.15.1 Federalwide Assurance Requirements

The Federalwide Assurance (FWA) commits the institution to compliance with the requirements set forth in 45 CFR Part 46, and the Terms of Assurance. Each institution that is engaged in HHS supported human subjects research must be covered by an FWA approved by OHRP.

When an applicant organization proposes non-exempt human subjects research and does not have a FWA, the AOR signature on the application constitutes declaration that the organization will comply with 45 CFR Part 46 and proceed to obtain a FWA. The NIH awarding component will place a restriction in the NoA so that no human subjects research may be conducted under the award until the FWA and certification of IRB review and approval (or certification of institutional determination of exemption, if applicable) have been obtained and accepted by NIH.

Each recipient institution must file its own FWA even if the organization does not operate its own IRB and designates another IRB for that purpose. IRBs must be registered with OHRP before the IRB may be designated on an FWA as reviewing proposed research for the FWA-holding institution.

Organizations that will serve as additional performance sites that are engaged in non-exempt human subjects research under the award must obtain an FWA, or, under specified circumstance, may be covered by the recipient's FWA in accordance with the OHRP's Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement.

It is the recipient organization's responsibility to ensure that all sites engaged in research involving human subjects are covered by an appropriate FWA and have IRB approval consistent with 45 CFR Part 46. It also is the recipient's responsibility to comply with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements). A list of organizations with approved assurances is available at the OHRP web site.

No individual may receive NIH grant funds for nonexempt research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an FWA or the individual makes other arrangements with OHRP.

Detailed information concerning FWAs is available on the OHRP web site.

4.1.15.2 Certification of IRB Approval

Recipients must provide a certification to NIH that all non-exempt human subjects research has been reviewed and approved by an appropriate IRB, consistent with 45 CFR Part 46 and OHRP guidance. The date of final IRB approval is the date that all protocols in the proposed research application received IRB review and approval (i.e., the date of the last protocol approval). When human subjects research is anticipated within the period of the award but definite plans for involvement of human subjects cannot be described in the application or proposal (referred to as "delayed onset human subjects research"), prior to the involvement of human subjects in non-exempt research, the recipient must submit to the NIH awarding IC for prior approval (1) detailed information as required in the Human Subjects and Clinical Trials Information Form of the application, as well as the certification and date of final IRB approval. Note that NIH requires the date of final IRB approval; conditional IRB approval is not sufficient. According to OHRP, in the case of IRB approval with conditions, IRB approval only becomes effective when the IRB has approved all information submitted in response to their conditions.

Certification of IRB approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with OHRP FWAs may wish to proceed with IRB review for those protocols that have not yet received IRB approval and that apply to applications in a fundable range.

Under no circumstances may NIH-supported non-exempt human subjects research be initiated prior to obtaining IRB approval and providing the final IRB approval date to NIH. NIH will not allow any funds to be used by recipients where a certification and an IRB approval date has not been provided to the funding IC.

Recipients are also reminded that any changes to study protocols that have been subject to peer review, as well as the addition of new study protocols, require the prior approval of the NIH awarding Institute or Center consistent with Section 8.1.2.5 of the NIHGPS. Such requirements are also generally described in the Funding Opportunity Announcement and/or the Notice of Award.

4.1.15.3 Reporting to Funding Agency and OHRP

Under the HHS regulations, recipient institutions must establish and follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and NIH of any unanticipated problem involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR Part

46 or IRB requirements or determinations; and any suspension or termination of IRB approval(revised Common Rule 45 CFR Part 46.108(a)(4) and pre-2018 Common Rule 45 CFR Part 46.103(b)(5)). Any IRB suspension or termination of approval must include a statement of the reasons for the IRB's action and must be reported promptly to the investigator, appropriate institutional officials, and NIH (45 CFR Part 46.113). Recipient institutions must also file incident reports promptly with OHRP of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 45 CFR Part 46 or with the requirements or determinations of the IRB, and suspension or termination of IRB approval. See OHRP 6/20/2011 *Guidance on Reporting Incidents to OHRP*.

4.1.15.4 OHRP Oversight

OHRP has regulatory responsibility for oversight of recipient compliance with the HHS human subjects regulations. In carrying out this responsibility, OHRP evaluates all written allegations or indications of non-compliance with the HHS regulations it receives from any source. All compliance oversight evaluations are predicated on the HHS regulations and the organization's assurance of compliance. Any corrective actions imposed as a result of a compliance oversight evaluation are intended to remedy identified non-compliance and prevent reoccurrence. Because each case is different, OHRP tailors corrective actions to foster the best interest of human research subjects and, to the extent possible, of the organization, research community, and HHS. Most compliance oversight evaluations and resultant corrective actions are resolved at the OHRP level. However, OHRP may recommend actions to be taken by other HHS officials.

Information about the FWA submission process and about OHRP activities related to oversight and compliance, as well as copies of the human subjects regulations, may be obtained from OHRP at the address shown in Part III or from its home page.

4.1.15.5 Education in the Protection of Human Research Participants

Before funds are awarded for competing applications involving human subjects, applicants must submit documentation that all senior/key personnel involved in human subjects research have received training in the protection of human subjects. Senior/key personnel include all individuals responsible for the design or conduct of the study, including senior/key personnel of consortium participants or alternate performance sites if they are participating in research that involves human subjects. This documentation should be included in the cover letter signed by the AOR that accompanies the description of other support, IRB and IACUC approval, and other information submitted prior to funding in accordance with Just-in-Time procedures. For non-competing continuation awards, the description of education for new senior/key personnel should be part of the progress report submitted as a prerequisite to award. Additional information about this education requirement is available on the NIH web site.

4.1.15.6 Data and Safety Monitoring

The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. NIH policies on data and safety monitoring specify that the level and frequency of monitoring should be commensurate with the risks, nature, and complexity of the clinical trial, and are in addition to any monitoring requirements imposed by FDA. There are a number of options for monitoring clinical trials including, but not limited to, monitoring by a/an:

- PD/PI (required),
- IRB (required),
- Independent individual/safety officer,
- Designated medical/research monitor,

- Internal committee or board with explicit guidelines,
- DSMB (required for multi-site trials).

Applications that include clinical trials must include a general description of the data and safety monitoring plan. The description of the data and safety monitoring plan in competing applications will be reviewed by the SRG. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It must describe the entity that will be responsible for monitoring how adverse events will be reported to the IRB and NIH and, when appropriate, how NIH Guidelines and FDA regulations for INDs and IDEs will be satisfied.

A detailed monitoring plan must be included as part of the research protocol, be submitted to the IRB, and be reviewed and approved by the NIH awarding IC prior to the accrual of human subjects. The awarding IC may specify the reporting requirements for adverse events, which are in addition to the annual report to the IRB. The clinical trial monitoring function is above and beyond that traditionally provided by IRBs; however, the IRB must be cognizant of the procedures used by clinical trial monitoring entities and the monitor must provide periodic reports to investigators for transmittal to the IRB.

NIH specifically requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials also may use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.

For multi-site Phase I and II trials, investigators should organize a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and the IRBs of participating sites. The frequency of summary reports will depend on the nature of the trial. Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and II clinical trials. However, such plans always should be evaluated for appropriateness for the particular investigation.

All multi-site trials with DSMBs are expected to forward summary reports of adverse events to each responsible IRB so they can address as appropriate to their responsibility reports related to the site. Recipients should address questions on this subject to the NIH PO.

Further information concerning these requirements is found on NIH's web site and in the application instructions (SF424 (R&R) and PHS 398).

4.1.15.7 Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

For all competing grant applications, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR Part 46 as well as with other pertinent federal laws and regulations.

Applications or proposals for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. Applications must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the recipient / offeror must provide an acceptable justification for the exclusion.

Scientific review groups at NIH will assess each application as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project, in addition to evaluating the plans for conducting the research in accord with these provisions. NIH staff will

monitor implementation of this policy during the development, review, award and conduct of research; and manage the NIH research portfolio to comply with the policy.

NIH recipients must submit data on participant age at enrollment in progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided to NIH in progress reports.

Ongoing, non-competing awards and competing applications submitted prior to January 25, 2019, will not be expected to comply with this policy until the recipient submits a competing renewal application. For these projects, the previous policy on the inclusion of children (NOT-98-024) continues to apply.

4.1.15.8 Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation

NIH-conducted and supported Clinical research must conform to the *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research* in accord with Public Health Service Act sec. 492B, 42 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations be included in NIH-conducted or supported clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the NIH IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification.

Cost is not an acceptable reason for exclusion except when the research would duplicate existing data. Women of childbearing potential should not be routinely excluded from participation in clinical research. The policy applies to research subjects of all ages in NIH-supported clinical research studies (see definition of clinical research). The inclusion of individuals on the basis of sex/gender, race, and ethnicity must be addressed in developing a research design appropriate to the scientific objectives of the study. A proposed outreach program for recruiting should also be included. When an NIH-defined Phase III clinical trial is proposed, investigators must consider whether clinically important sex/gender, racial, and/or ethnic differences in the intervention effect are to be expected and plan the research accordingly. When registering in Clincialtrials.gov, applicable clinical trials as defined in 42 C.F.R. Part 11, that are also NIH-defined Phase III clinical trials must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. For applicable clinical trials that are also NIH-defined Phase III clinical trials, submissions of results to Clinicaltrials.gov must include results of valid analyses by sex/gender and race/ethnicity, as required based on prior evidence.

Investigators must also collect and annually report information on sex/gender, race, and ethnicity in clinical research studies. The OMB minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant projects are described in OMB Directive No. 15. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards include five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for ethnicity: “Hispanic or Latino,” and “Not Hispanic or Latino.”

For more information on policies and procedures related to inclusion: Inclusion Procedures

4.1.15.9 Good Clinical Practice Training for NIH Recipients Involved in NIH-funded Clinical Trials

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6 (R2).

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting of clinical trials.

GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The principles were developed in 1996 by the ICH in collaboration with representatives from the European Union, Japan, and the United States. The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.

GCP describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with GCP provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.

GCP training complements other required training on protections for human research participants. Since June 2000, the NIH Extramural Research Program has required training on protections for human research participants for all NIH-funded investigators and individuals responsible for the design or conduct of NIH funded research involving human subjects.

The GCP policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials. GCP training includes the Principles of ICH GCP found in Section 2 of ICH E6. GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. Acceptable GCP courses include the NIAID GCP Learning Center website and National Drug Abuse Treatment Clinical Trials Network.. Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training, and make it available to NIH upon request.

For purposes of Good Clinical Practice training the following definitions apply:

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical trial staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

4.1.15.10 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

NIH requires sites engaged in NIH-funded, multi-site research conducted at more than one domestic site to rely upon approval by a single Institutional Review Board (sIRB) as required by the Revised Common Rule (rCR) at 45 CFR Part 46.114 and NIH sIRB Policy, including projects supported by career development (K) and fellowship (F) awards with initial IRB approval on or after January 20, 2020. Foreign sites participating in NIH-funded, multi-site studies will not be expected to use a single IRB.

NIH applicants whose research is subject to the sIRB requirements must provide the name of the sIRB during the Just-in-Time period, before the award is issued. If, in delayed-onset research, an sIRB has not yet been identified, the recipient will provide the name of the sIRB to the funding NIH Institute/Center (IC) prior to initiating the multi-site research study/project.

The applicant may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study/project by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, as described in Chapter 7 (Cost Consideration) and in case of commercial organizations the Federal Acquisition Regulation (FAR) 31.302 (Direct Costs) and FAR 31.203 (Indirect Costs).

Recipients are responsible for ensuring that authorization agreements are in place. Copies of authorization agreements and other necessary documentation should be maintained to document compliance, as needed. As appropriate, recipients are responsible for ensuring that a mechanism for communication between the sIRB and participating sites is established.

All sites participating in multi-site research studies/projects subject to the sIRB requirements are expected to rely on an sIRB to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR Part 46. Participating sites are responsible for meeting all other regulatory obligations.

NIH sIRB policy does not prohibit participating sites from also reviewing the research under the applicable regulatory framework. This additional review, even if performed by the institution's IRB, is not the regulatory review of the research as that responsibility still remains with the sIRB. Iif this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review

4.1.16 Investigational New Drug Applications/Investigational Device Exceptions

To be eligible for NIH funding, all clinical research involving investigational drugs and devices, or other products regulated by the FDA, must comply with all applicable FDA requirements, including those for INDs, IDEs, and human subjects protections. Among other provisions, FDA regulations for human subjects protections are published in 21 CFR Parts 50 and 56 with additional standards found in Parts 312 and 812.

When applicable, the sponsor of the IND/IDE, whether NIH, a recipient, or a third party, is legally responsible for meeting the FDA requirements for sponsors. If the sponsor is also the PI, then the sponsor will need to satisfy FDA’s requirements for sponsor-investigators. If the IND/IDE sponsor is a third party, such as a pharmaceutical company or research organization under contract to a recipient or to a pharmaceutical company, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the sponsor rather than the recipient. This generally will be the case for larger, multi-site clinical trials. If the recipient is the IND/IDE holder, commonly referred to as an “investigator-initiated IND/IDE,” the recipient or the investigator serves as the sponsor and assumes the legal responsibility. In

any case, the recipient is ultimately responsible to NIH for ensuring compliance with the applicable requirements for protection of human subjects, including compliance with FDA's requirements.

Following the filing of an IND, FDA has a 30-day period in which to review it. FDA may allow the IND to proceed or may defer approval of the IND until changes it deems acceptable are made. FDA also may order a clinical trial to be suspended or terminated, at any time, based on information it receives about that clinical trial.

When NIH funds any part of a clinical study involving an IND or an IDE, NIH must be knowledgeable about any significant communications with FDA concerning the study. The recipient organization must report certain types of FDA communications to the NIH awarding IC within 72 hours of receiving a copy of, or upon being informed of, the FDA communication (through the PD/PI or another person acting on behalf of the recipient), whichever occurs first. This notification requirement applies to any of the following communications from FDA with the sponsor of the IND or IDE:

- Warning letters (whether sent to the recipient or to the commercial sponsor)
- Notices of Initiation of Disqualification Proceedings and Opportunity to Explain
- Notice of Opportunity for Hearing
- Notice of Disqualification
- Consent Agreements
- Clinical hold letters that pertain to breaches of good manufacturing practices, good clinical practices, or other major issue requiring significant changes in the protocol.

The notification should be made in writing, but also may be done by telephone if a written notice would delay the notification. It should include a statement of the action taken or contemplated and the assistance needed to resolve the situation. These requirements apply to the recipient even if the recipient or the NIH-funded PD/PI is the sponsor. Failure to comply with this requirement may result in NIH imposing a corrective and/or enforcement action (see Administrative Requirements—Enforcement Actions). FDA communications are considered grant-related records for purposes of retention and access (see Administrative Requirements—Monitoring—Record Retention and Access).

4.1.17 Lobbying Prohibition

Recipients of Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR Part 93, which also describes types of activities, such as legislative liaison activities and professional and technical services, which are not subject to this prohibition under certain circumstances.

Applicants for NIH awards are required to certify and disclose that they:

- have not made, and will not make, such a prohibited payment;
- used or will use non-appropriated funds if they have made or agreed to make such payment; and
- will include these requirements in consortium agreements and contracts under grants that will exceed $100,000 and obtain necessary certifications from those consortium participants and contractors.

Certifications and disclosures must be filed at the times prescribed in the regulations based on the expected total costs.

The signature of the AOR on the application serves as the required certification of compliance for the applicant organization. Disclosure reporting is addressed in Administrative Requirements—Monitoring—Reporting.

See also Appropriation Public Policy Requirements Mandates Lobbying—Appropriation Prohibition for additional restrictions.

4.1.18 Metric System

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, measurement values in applications and recipient-prepared reports, publications, and other grant-related documents should be in metric. See Construction Grants chapter in IIB for requirements for metric usage in construction activities.

4.1.19 Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education

Section 588 of the National Defense Authorization Act of 1995, amended (10 U.S.C. §983), precludes NIH grant awards to institutions of higher education that DoD determines have an anti-Reserve Officer Training Corps (ROTC) policy or practice (regardless of when implemented) that either prohibits or, in effect, prevents the Secretary of Defense from gaining entry to campuses or access to students or information for military recruiting. DoD publishes each determination of ineligibility in the Federal Register as well as publishing, once every 6 months, a list of all currently ineligible schools. If DoD determines that an institution is ineligible during an ongoing project period, NIH will suspend support of current and future grant awards as provided in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support. Funding eligibility may be restored on the basis of new information provided by DoD.

4.1.20 National Environmental Policy Act

All NIH grants, whether or not they include construction or major A&R activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended. This Act requires Federal agencies to consider the reasonably foreseeable environmental consequences of all grant-supported activities. As part of NIH's implementation of this Act, recipients are required to promptly notify NIH of any reasonably foreseeable impacts on the environment from grant-supported activities, or certify that no such impacts will arise upon receipt of a grant award. In addition, NIH has determined that most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.

4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

This requirement is in addition to other public policy requirements for grants for construction and alteration and renovation activities discussed more fully in the Construction chapter - Construction, Modernization, or Major Alteration and Renovation of Research Facilities—Public Policy Requirements.

4.1.21 Nondelinquency on Federal Debt

The Federal Debt Collection Procedures Act of 1990 (Act), 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the AOR of the applicant organization (or individual in the case of a Kirschstein-NRSA individual fellowship) certifies, by means of their signature on the application, that the organization (or individual) is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or satisfactory arrangements made, NIH will take that delinquency into account when determining whether the applicant would be a responsible NIH grant recipient.

Anyone who has been judged to be in default on a Federal debt and who has had a judgment lien filed against them should not be listed as a participant in an application for an NIH grant until the judgment is paid in full or is otherwise satisfied. No funds may be used for or rebudgeted following an award to pay such an individual. NIH will disallow costs charged to awards that provide funds to individuals in violation of this Act.

These requirements apply to all types of organizations and awards, including foreign grants.

4.1.22 President's Emergency Plan for AIDS Relief (PEPFAR) Program

4.1.22.1 PEPFAR Agreements

Specific terms and conditions concerning prostitution and sex trafficking apply to all grants awarded under the U.S. President’s Emergency Plan for AIDs Relief (PEPFAR) program. These are:

A. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

B. The following definitions apply for purposes of this provision:
    1. "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.
    2. "Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.
    3. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.

C. The Recipient must insert this provision, which is a standard provision, in all subawards or subcontracts.

D. This provision includes express terms and conditions of the award and any violation of it is grounds for unilateral termination of the award by NIH prior to the end of its term.

4.1.22.2 PEPFAR Agreements Between the U.S. Government and Foreign Non-Governmental Organizations (NGOs)

Additional requirements regarding the opposition to prostitution and sex trafficking may be applied to grants awarded under PEPFAR and issued to foreign Non-Governmental Organizations (NGOs) directly supported by or subrecipients of U.S. public or private NGOs. Subject to the United States Supreme Court's decision in Agency for International Development, et al., v. Alliance for Open Society International, Inc., et al., 133 S. Ct. 2321 (2013) and subsequent proceedings, the terms and conditions for such agreements with foreign NGOs may include the following:

A. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

B. 1. Except as provided in (B)(2) and (B)(3), by accepting this award or any subaward, a non-governmental organization or public international organization recipient / sub-recipient agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children. Any enforcement of this clause is subject to *Agency for International Development, et al., v. Alliance for Open Society International, Inc., et al.*, 133 S. Ct. 2321 (2013) and subsequent proceedings.

2. The following organizations are exempt from (B)(1): the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.

3. Contractors and subcontractors are exempt from (B)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.

4. Notwithstanding section (B)(3), not exempt from (B)(1) are recipients, subrecipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any subaward, or procurement contract or subcontract by:

   i. Providing supplies or services directly to the final populations receiving such supplies or services in host countries;

   ii. Providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or

   iii. Providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).

C. The following definitions apply for purposes of this provision:

1. "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.

2. "Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.

3. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

D. The recipient shall insert this provision, which is a standard provision, in all subawards, procurement contracts or subcontracts.

E. This provision includes express terms and conditions of the award and any violation of it shall be grounds for termination of the award by NIH prior to the end of its term.

4.1.23 Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH grants are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library

services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient substance or alcohol treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH grant should be directed to the GMO.

4.1.24 Public Health Security

4.1.24.1 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. 201, is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the U.S. homeland or other criminal acts. The Act was implemented, in part, through regulations published by HHS and USDA at 42 CFR Part 73, 9 CFR Part 121 and 7 CFR Part 331 or commonly referred to as "Select Agent Regulations." Copies of these regulations are available here, or can be obtained from CDC, 1600 Clifton Road, MS A-46, Atlanta, GA 30333; telephone: 404-718-2000.

Research involving select agents and recombinant or synthetic nucleic acid molecules also is subject to *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. *NIH Guidelines* apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of *NIH Guidelines* are available.

4.1.24.1.1 Select Agents

4.1.24.1.1.1 Select Agent Awards to U.S. Institutions

Domestic recipients who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR Part 73 and 9 CFR Part 121 and Section 3 of 7 CFR Part 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

4.1.24.1.1.2 Select Agent Awards to Foreign Organizations and International Organizations

Foreign Organizations and International Organizations who conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must provide information satisfactory to NIH that a process equivalent to that

described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by NIH funds before using these funds for any work directly involving select agents. Recipients must be willing to address the following key elements appropriate for their institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

4.1.24.1.1.3 Select Agent Awards to U.S. Institutions with Foreign Subcomponents

Recipients who conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must complete registration with CDC (or USDA, depending on the agent) before using NIH funds for any work directly involving the select agent at the U.S. institution. No funds can be used for research involving select agents if the final registration certificate is denied. Before using NIH funds for any work directly involving the select agents at a foreign subrecipient, the U.S. recipient must provide information from the foreign organization satisfactory to NIH that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by these funds. Recipients must be willing to address the following key elements appropriate for the foreign organization: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73 are followed. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

4.1.24.2 Dual Use Research of Concern

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC). DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Despite its value and benefits, some research may be misused for harmful purposes. The fundamental aim of this oversight policy is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

The DURC policy applies to recipients institutions and its investigators in the United States that receive Federal funding for life sciences research and that conduct or sponsor research involving one or more of the 15 agents or toxins listed in the policy and to foreign recipients that receive Federal funding to conduct or sponsor research involving one of these 15 agents or toxins. Institutions must establish an Institutional Review Entity (IRE) which must review research involving these agents or toxins to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR), as required by the U.S. Government's DURC Policy, to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of the DURC policy role. The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

For research that may be considered DURC, NIH will work collaboratively with the institution and investigators to develop a risk mitigation plan, which may be implemented through a term of award and that NIH must approve. For example, NIH may request that institutions periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official prior to submitting the manuscript to a journal.

4.1.24.3 Agents Regulated Under the Chemical Weapons Convention

The United States is one of 175 States Parties to the Chemical Weapons Convention (CWC), which prohibits the development, production, stockpiling, and use of chemical weapons (CW). The CWC does not prohibit production, processing, consumption, or trade of related chemicals for peaceful purposes, but it does establish a verification regime to ensure such activities are consistent with the object and purpose of the treaty.

NIH researchers engaged in activities involving these chemicals, especially Schedule 1 chemicals, may be required to submit declarations and/or reports to the Bureau of Industry and Security (BIS) and may be subject to inspection by the Organization for the Prohibition of Chemical Weapons, which administers the CWC. In addition, trade in certain chemicals with States not Party to the CWC may be prohibited or subject to an export license and or end-use certificate.

Schedule 1 chemicals include, but are not limited to, the toxic chemicals sarin, soman, tabun, VX, sulfur mustards, Lewisites, saxitoxin, ricin, and nitrogen mustards. More information about the U.S. CWC, including complete lists of Schedule 1, 2, and 3 chemicals under the CWC may be found at http://www.cwc.gov/index.html. Federal regulations that apply to the CWC are 15 CFR CHAPTER VII, SUBCHAPTER B, PARTS 710-722, SUBCHAPTER C, PARTS 730-774; 22 CFR CHAPTER I, PART 103, PARTS 120-130. These CRFs and other applicable safety standards issued by the Department of Commerce and Department of State are available at http://www.cwc.gov/regulations_cwc_regulations.html.

4.1.25 Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees

As required by Section 403C of the Public Health Service Act, each institution receiving an NIH award for the training of graduate students for doctoral degrees must provide information on completion rates and time to degree to all applicants to doctoral programs supported by NIH training awards. Specifically, institutions must provide applicants with the following information for the programs to which they apply:

- The percentage of students admitted for study who successfully attain a doctoral degree, and
- The average time (not including any leaves of absence) between the beginning of graduate study and the receipt of a doctoral degree.

Institutions **affected** by this Assurance and information disclosure requirement are doctoral degree granting institutions that receive any of the following institutional training grant awards or cooperative agreements from NIH for the doctoral training of graduate students:

- D43, TU2, T15, T32, T37, T90, U2R, U90, and U54/TL1

Institutions are **not affected** by this requirement if they:

- Receive only individual NIH fellowship awards.
- Provide training only to undergraduate or master's level students supported through one of the activity codes listed above.
- Provide only short-term training to doctoral-level health professional students through one of the activity codes listed above.
- Receive an award for one or more of the activity codes for doctoral training of graduate students, but do not confer doctoral degrees themselves (e.g., teaching hospitals).
- Receive an institutional training grant award for doctoral training of graduate students from a Public Health Service Agency other than NIH.

In complying with this Assurance and information disclosure requirement, institutions may decide how best to present the required information to applicants and may wish to consider consolidating data by department or broad program to which candidates apply, or providing additional information in order to provide context.

Recipients with awards for any of the activity codes listed above are also required to provide corresponding information on trainees supported by each of their awards when submitting a renewal application or RPPR.

4.1.26 Research Involving Recombinant or Synthetic Nucleic Acid Molecules (including Human Gene Transfer Research)

4.1.26.1 Scope and Availability

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (April 2019 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research.

According to *NIH Guidelines*, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3)molecules that result from the replication of those described in (1) or (2). *NIH Guidelines* apply to both basic and clinical research studies.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. The recipient should carefully review *NIH Guidelines* in its entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.

Recombinant or synthetic nucleic acid research involving select agents also is subject to pertinent CDC and USDA regulations, 42 CFR Part 73, Select Agents and Toxins; and 7 CFR Part 331 and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins.

4.1.26.2 Institutional Biosafety Committee

Each organization that conducts research involving recombinant or synthetic nucleic acid molecules, including contractors under grants, must have policies and procedures to ensure compliance with *NIH*

Guidelines and must establish a standing IBC. The IBC is required to review each proposed project for recombinant or synthetic nucleic acid molecule experiments to ensure that the procedures, project, personnel, and facilities are adequate and in compliance with *NIH Guidelines*. Section IV of *NIH Guidelines* specifies the composition of IBCs. A roster of the IBC members and biosketches for each member must be submitted to NIH. At a minimum, the roster should indicate the name of each IBC member, as well as which IBC members are serving as the chairperson, contact person, and, as applicable, experts in biosafety or plant, animal, or human experimentation. Biosketches should include a description of the occupation and professional qualifications of each member. Organizations can register their IBC with NIH on-line by utilizing the IBC Registration Management System (RMS).

4.1.26.3 Investigators and Institutional Staff

Section IV of *NIH Guidelines* also specifies the roles and responsibilities of PIs, biological safety officers (BSOs) and recipient institutions with respect to the safe conduct and oversight of recombinant or synthetic nucleic acid research. Investigators, laboratory staff, BSOs, and institutional officials should read and be aware of their duties and expected biosafety practices, as described by *NIH Guidelines*.

4.1.27 Research Misconduct

Title 42 CFR Part 93, PHS Policies on Research Misconduct (the "PHS regulation"), Subpart C, "Responsibilities of Institutions" specifies recipient responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity. Research misconduct is defined by Subpart A of 42 CFR Part 93 as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Subpart D, "Responsibilities of the U.S. Department of Health and Human Services," specifies that ORI has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities (http://www.ori.dhhs.gov).

To be eligible for PHS funding, domestic and foreign institutions must have approved assurances and required renewals on file with ORI. The responsible institutional official must assure on behalf of the institution that the institution (1) has written policies and procedures in compliance with 42 CFR Part 93 for inquiring into and investigating allegations of research misconduct in PHS-supported research and (2) complies with its own policies and procedures and the requirements of 42 CFR Part 93. In addition, recipient institutions must foster a research environment that promotes the responsible conduct of research. Domestic and foreign subrecipient institutions must also maintain an assurance by submitting form PHS-6315 to ORI. An institution establishes an assurance when an official signs the face-page (SF 424 (R&R) or PHS 398) of the grant application form or when the institution files a separate assurance form. Once established, institutions maintain their assurance by filing the Annual Report on Possible Research Misconduct (between January 1 and March 1 each year), submitting their policy for responding to allegations of research misconduct for review when requested by ORI, revising their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and complying with the PHS regulation.

As stated throughout the NIHGPS, the recipient has primary responsibility for ensuring that it is conducting its NIH-funded project in accordance with the approved application and budget and the terms and conditions of the award. The recipient must carry out its responsibilities with extra care where research misconduct has been found or where a research misconduct investigation has been initiated, as specified in 42 CFR Part 93, Subpart C. The recipient must report promptly to ORI any decision to initiate an investigation of research misconduct.

The regulations specify the timing of an institutional investigation, related reporting to ORI, notice to the respondent, custody of records, documentation, opportunity for respondent to comment on the report, and the components on a final institutional investigative report.

If a misconduct investigation is initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and live vertebrate animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to provide technical assistance to any institution that is responding to an allegation of research misconduct involving PHS funds. NIH IC staff members are available to provide guidance and to work with recipient institutions to protect funded projects from the adverse effects of research misconduct.

The recipient institution's engagement with ORI as provided in 42 CFR Part 93 does not substitute for its engagement with NIH to ensure ongoing compliance with the terms and conditions of award. When the recipient institution finds, learns of, or suspects research misconduct that impacts or might impact the conduct or performance of an NIH-supported project(s), whether at the recipient organization or at a third-party subrecipient organization, the recipient must work with NIH to assess the effect on the ability to continue the project, as originally approved by NIH. If the recipient institution determines that a change of scope or a change of PD/PI or other senior/key personnel is required, the institution must promptly obtain approval from the NIH funding Institute or Center Grants Management Officer. When a recipient institution finds, learns, or suspects that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research, including but not limited to, applications for funding and progress reports, or published research or research products supported by NIH funds, NIH has a need to know this information, and the institution must immediately provide information on the affected research to the NIH Office of Extramural Research – Research Integrity (OER-RI), in a manner consistent with the ORI confidentiality provision at, 42 CFR Part 93.108. The final institutional investigation report must be submitted to ORI, as outlined in Subpart C of 42 CFR Part 93.

NIH retains the authority to provide oversight regarding the management of grants and cooperative agreements. Accordingly, NIH may take action(s) to protect the health and safety of the public, including research participants, to promote the integrity of the PHS supported research and research process, and to conserve public funds. When a recipient fails to comply with the terms and conditions of award, NIH may take one or more enforcement actions including disallowance of costs, withholding of further support, or suspension or termination of the grant. These actions are described in Administrative Requirements—Enforcement Actions.

Where research misconduct has affected data validity or reliability, ORI or NIH may request that the recipient and its employee/collaborator authors submit a correction or retraction of the data to a journal, publish the corrected data, or both. If the recipient does not comply, NIH may invoke its rights, under 2 CFR Part 200.315 and 45 CFR Part 75.322, to access the data (including copyrightable material developed under the award), and may then have the data reviewed, and notify the journal.

4.1.28 Seat Belt Use

Pursuant to EO 13043 (April 16, 1997), Increasing the Use of Seat Belts in the United States, NIH encourages recipients to adopt and enforce on-the-job seat belt policies and programs for their employees when operating vehicles, whether organizationally owned or rented or personally owned.

4.1.29 Smoke-Free Workplace

NIH strongly encourages recipients to provide smoke-free workplaces and to promote the nonuse of tobacco products. NIH defines the term "workplace" to mean office space (including private offices and other workspace), conference or meeting rooms, corridors, stairways, lobbies, rest rooms, cafeterias, and other public spaces.

4.1.30 Standards of Conduct

NIH requires recipients to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, NIH does not require a recipient to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State and local laws and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas as political participation and bribery. The standards also must do the following:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper.
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official.
- Include a process for notification and review by the responsible official of potential or actual violations of the standards.
- Specify the nature of penalties that the recipient may impose. These penalties would be in addition to any penalties that NIH or a cognizant Federal agency may impose for infractions that also violate the terms or conditions of award.

The recipient is not required to submit its general standards of conduct to NIH for review or approval. However, a copy must be made available to each of its officers, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, to NIH. The recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, the recipient is required to notify the NIH of an identified financial conflict of interest (FCOI) by submitting the FCOI report to NIH via the eRA Commons FCOI Module (see 4.1.10, Financial Conflict of Interest). If a suspension or separation action is taken by a recipient against a PD/PI or other senior/key personnel under an NIH grant, the recipient must request prior approval of the proposed replacement as specified in Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements.

The recipient must promptly report issues involving potential criminal violations, such as misappropriation of Federal funds, to the HHS OIG .

4.1.31 Text Messaging While Driving

Executive Order 13513 (E.O. 13513) requires each Federal agency to encourage contractors, subcontractors, and grant and cooperative agreement recipients and subrecipients to adopt and enforce policies that ban text messaging while driving company-owned or -rented vehicles or Government Owned Vehicles, or while driving Personally Owned Vehicles when on official Government business or when performing any work for or on behalf of the Government.

To further the requirement of encouraging such policies, NIH encourages recipients to consider new rules and programs, reevaluate existing programs to prohibit text messaging while driving, and conduct education, awareness, and other outreach for employees about the risks associated with texting while driving. These initiatives should encourage voluntary compliance with the recipient agency's text messaging policy while off duty.

For the purposes of this policy and pursuant to E.O. 13513, the following definitions apply:

a. ''Texting'' or ''Text Messaging'' means reading from or entering data into any handheld or other electronic device, including for the purpose of SMS texting, e-mailing, instant messaging, obtaining navigational information, or engaging in any other form of electronic data retrieval or electronic data communication.

b. ''Driving'' means operating a motor vehicle on an active roadway with the motor running, including while temporarily stationary because of traffic, a traffic light or stop sign, or otherwise. It does not include operating a motor vehicle with or without the motor running when one has pulled over to the side of, or off, an active roadway and has halted in a location where one can safely remain stationary.

4.1.32 Trafficking in Persons

This government-wide award term implements Section 106 (g) of the Trafficking Victims Protection Act (TVPA) of 2000, as amended (22 U.S.C. 7104), located at 2 CFR Part 175.A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance. A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance.

In accordance with the statutory requirement, in each agency award under which funding is provided to a private entity, section 106(g) of the TVPA, as amended, requires the agency to include a condition that authorizes the agency to terminate the award, without penalty, if the recipient or a subrecipient —

a. Engages in severe forms of trafficking in persons during the period of time that the award is in effect;

b. Procures a commercial sex act during the period of time that the award is in effect; or

c. Uses forced labor in the performance of the award or subawards under the award.

4.1.33 USA Patriot Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. "Restricted persons," as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent (see Public Health Security and Bioterrorism Preparedness and Response Act in this section).

4.1.34 Federal Awardee Performance and Integrity Information System (FAPIIS)

NIH award recipients are subject to the reporting requirements established by Public Law 112-239, National Defense Authorization Act for Fiscal Year 2013 and provided in Appendix XII to 2 CFR Part

200 and 45 CFR Part 75, Appendix XII, NIH recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200 and 45 CFR Part 75, Appendix XII.

The FAPIIS Public Access - Search Page is provided at https://www.fapiis.gov/fapiis/#/home.

4.1.35 Mandatory Disclosures

Consistent with 2 CFR Part 200.113 and 45 CFR Part 75.113, NIH applicants and recipients must disclose, in a timely manner, in writing to the NIH awarding IC and the HHS Office of Inspector General (OIG) all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially impacting the federal award. Subrecipients must disclose, in a timely manner, in writing to the prime recipient (pass-through entity) and the HHS OIG all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the NIH awarding IC and to the HHS OIG at the following address:

NIH CGMO listed on the NoA for the IC that funded the grant (See Part III: Points of Contact 20 INSTITUTES AND CENTERS)

AND

U.S. Department of Health and Human Services

Office of Inspector General

ATTN: Mandatory Grant Disclosures, Intake Coordinator

330 Independence Avenue, SW, Cohen Building

Room 5527

Washington, DC 20201

URL: https://oig.hhs.gov/fraud/report-fraud/index.asp

(Include "Mandatory Grant Disclosures" in the subject line")

Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or

Email: MandatoryGranteeDisclosures@oig.hhs.gov

Failure to make required disclosures can result in any of the remedies described in 2 CFR Part 200.339 and 45 CFR Part 75.371. Remedies for noncompliance and Administrative Requirements – Enforcement Actions, including suspension or debarment (See 2 CFR Part 180 and 376, 31 U.S.C.3321 and Public Policy Requirements and Objectives— Debarment and Suspension), as necessary and appropriate.

4.1.36 Never Contract with the Enemy

Federal awarding agencies and recipients are subject to the regulations implementing Never Contract with the Enemy in 2 CFR Part 183. The regulations in 2 CFR Part 183 affect covered contracts, grants and cooperative agreements that are expected to exceed $50,000 within the period of performance, are performed outside the United States and its territories, and are in support of a contingency operation in which members of the Armed Forces are actively engaged in hostilities.

4.1.37 Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

Recipients and subrecipients are prohibited from expending loan or grant funds to: (1) Procure or obtain; (2) Extend or renew a contract to procure or obtain; or (3) Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

(i) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

(ii) Telecommunications or video surveillance services provided by such entities or using such equipment.

(iii) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

COVERED FOREIGN COUNTRY means the People's Republic of China.

In implementing the prohibition under section 889 of the NDAA, subsection (f), paragraph (1), heads of executive agencies administering loan, grant, or subsidy programs shall prioritize available funding and technical support to assist affected businesses, institutions and organizations as is reasonably necessary for those affected entities to transition from covered communications equipment and services, to procure replacement equipment and services, and to ensure that communications service to users and customers is sustained.

4.2 APPROPRIATION MANDATES

The following statutory provisions limit the use of funds on NIH grants, cooperative agreements, and contract awards. These are provided separately in this section since they are subject to change annually based on specific appropriation language that restricts the use of grant funds. References to "Act" in these sections refer to the governing HHS annual appropriation Act. A list of Appropriation Mandates applicable to each fiscal year can be found on the OER web site.

4.2.1 Acknowledgment of Federal Funding

In accordance with Public Law 101-166, Section 511, known as the Steven's Amendment, all HHS recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Recipients are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and (2) the dollar amount of the total costs financed by nongovernmental sources, only for NIH programs that require cost-sharing.

4.2.3 Dissemination of False or Deliberately Misleading Information

None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading.

4.2.4 Gun Control

NIH funds may not be used, in whole or in part, to advocate or promote gun control.

4.2.5 Human Embryo Research and Cloning Ban

NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term “human embryo or embryos” includes any organism not protected as a human subject under 45 CFR Part 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. Furthermore, per the NIH Director’s Statement of April 28, 2015, NIH will not fund any use of gene-editing technologies in human embryos.

In addition to the statutory restrictions on human fetal research under subsection 498((b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

4.2.6 Lobbying—Appropriation Prohibition

NIH appropriated funds may not be used, other than for normal and recognized executive-legislative relationships for publicity or propaganda purposes, for the preparation, distribution, or use of a kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State legislature or local legislature itself or designed to support or defeat any proposed or pending regulation administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself. No part of any governing appropriation act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in

policymaking and administrative processes within the executive branch of that government. No part of any governing appropriation Act shall be used for any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control, except as described above. Also see Public Policy Requirements and Objectives—Lobbying Prohibition, Appropriation Mandates—Gun Control and Cost Considerations—Allowability of Costs and Activities.

4.2.7 Promotion or Legalization of Controlled Substances

Recipients are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the recipient notifies the GMO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage (see also Public Policy Requirements/Controlled Substances).

4.2.8 Restriction on Abortion Funding

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion. The term ‘‘health benefits coverage’’ means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

4.2.8.1 Exceptions to Restrictions on Abortions

A. The limitations established in the preceding section shall not apply to an abortion —
    1. If the pregnancy is the result of an act of rape or incest; or
    2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

B. Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State’s or locality’s contribution of Medicaid matching funds).

C. Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State’s or locality’s contribution of Medicaid matching funds).

D. 1. None of the funds appropriated to NIH may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

2. In this subsection, the term ‘‘health care entity’’ includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

4.2.9 Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. However, this limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law

4.2.10 Salary Cap/Salary Limitation

None of the funds appropriated in the governing appropriation Act for NIH (the Act), shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation. Current and historical information on the applicable salary cap for each fiscal year is on the OER Salary Cap Summary web page.

4.2.11 Restriction of Pornography on Computer Networks

“(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.”

4.2.12 Restriction on Disclosure of Political Affiliation for Federal Scientific Advisory Committee Candidates

“None of the funds made available in this Act may be used to request that a candidate for appointment to a Federal scientific advisory committee disclose the political affiliation or voting history of the candidate or the position that the candidate holds with respect to political issues not directly related to and necessary for the work of the committee involved.”

5 THE NOTICE OF AWARD

The Notice of Award (NoA) is the legal document issued to notify the recipient that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. The NoA reflects any future-year commitments. A revised NoA may be issued during a budget period to affect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. NIH will not issue a revised NoA to reflect a recipient's post-award rebudgeting. Until an IC has issued the NoA for the initial award, any costs incurred by the applicant for the project are incurred at its own risk (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs for NIH policy on the allowability of pre-award costs).

Notice of Award Page One

Effective October 1, 2020, HHS implemented a standardized page one of the NoA that serves as the first page of every HHS NoA for all discretionary awards. The standardized page one incorporates the following data elements:

- HHS Operating Division
- Federal Award Identification Number
- Federal Award Date

- Recipient Information
  - Recipient Name
  - Congressional District of Recipient
  - Payment System Identifier (also known as Entity Identification Number)
  - Employer Identification Number
  - Data Universal Numbering System
  - Recipient's Unique Entity Identifier
  - Project Director or Principal Investigator
  - Authorized Official
- Federal Agency Information
  - Awarding Agency Contact Information
  - Program Official Contact Information
- Federal Award Information
  - Award Number
  - Unique Federal Award Identification Number
  - Statutory Authority
  - Federal Award Project Title
  - Assistance Listing Number (formerly / also known as CFDA Number)

        - Assistance Listing Program Title (formerly / also known as CFDA program title)Name)
        - Award Action Type
        - Is this Award R&D?
        - Summary Federal Award Financial Information
            - Budget Period Start and End Date
            - Total Amount of Federal Funds Obligated by this Action
                - Direct Cost Amount
                - Indirect Cost Amount
            - Authorized Carryover
            - Offset
            - Total Amount of Federal Funds Obligated this Budget Period
            - Total Approved Cost Sharing or Matching, where applicable
            - Total Federal and Non-Federal Approved this Budget Period
            - Project Period Start and End Date
            - Total Amount of the Federal Award, including Approved Cost Sharing or Matching, this Project Period
    - Authorized Treatment of Program Income
    - Grants Management Officer Signature
    - Remarks

Remainder of the NIH NoA

Additionally, the remainder of the NIH NoA sets forth pertinent information about the grant in Section I (Award Data), Section II (Payment Information), and Sections III and IV (Applicable Terms and Conditions of Award). This additional information, includes, but not limited to, the following:

- Cumulative budget approved by the NIH awarding IC
- Amount of anticipated future-year commitments (if applicable)
- Names of the cognizant IC PO, GMO, and GMS
- Indirect cost rate for the Federal award (including if the de minimis rate is charged per 2 CFR Part 200.414 and 45 CFR Part 75.414)
- Applicable terms and conditions of award, either by reference or inclusion
- Federal award performance goals (as required by the periodic report in the RPPR or in the final RPPR when applicable)
- Any restriction on the use of funds

Note: If applicable, section III of the NoA will also reference an institution’s participation in the current phase of the Federal Demonstration Partnership (FDP).

As specified in the NoA, all awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

A recipient indicates acceptance of an NIH award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. If the recipient cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the GMO immediately upon receipt of the NoA. If resolution cannot be reached, the GMO will void the grant. NIH's determination of applicable terms and conditions of award or a GMO's denial of a request to change the terms and conditions is discretionary and not subject to appeal (post-award appeal rights are discussed in Administrative Requirements—Grant Appeals Procedures). Once the award is accepted by the recipient, the contents of the NoA are binding on the recipient unless and until modified by a revised NoA signed by the GMO.

5.1 NOTICE OF AWARD NOTIFICATION

NIH notifies the recipient organization via e-mail when an award has been issued-i.e., on the Federal award date. In order to allow for the e-mail notification of the NoA, recipient organizations must register a valid e-mail address in the NoA E-mail field in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. Organizations are encouraged to use a unique e-mail address that is not specific to an individual in order to avoid communication problems when personnel change. It is the responsibility of the recipient organization to maintain a current and accurate e-mail address for NoAs. NIH will not distribute NoAs other than through this system-generated e-mail notification process. Recipients that do not maintain a current NoA notification e-mail address will be responsible for accessing NoAs via the eRA Common.

On the Federal award date, the NoA is made available to recipient officials and corresponding PD/PIs in the eRA Commons through the Status module. The eRA Commons is the official repository for the NoA document.

In addition to e-mail notifications, there is a public query *Issued Notice of (Grant) Award* available on the eRA web site to generate a list of awards issued to an organization over a selected period. The organization's Institution Profile File (IPF) Number is required in order to use the query.

5.2 ASSOCIATED APPLICATIONS AND/OR AWARDS

For some special initiatives a project or program may be funded by multiple awards that are associated with the others through specific terms and conditions. These terms include any reporting requirements that would need to be coordinated in future years. When multiple awards are issued for a particular project/program at different institutions, the coordination required among the recipient institutions administering the awards will be documented in the specific terms and conditions.

5.3 FUNDING

For most grants, NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget

periods. The length of an initial project period (competitive segment) or of any subsequent competitive segment is determined by the NIH awarding IC based on:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete the project,
- limitation on the length of the project period recommended by the peer reviewers,
- the awarding IC's programmatic determination of the frequency of competitive review desirable for managing the project, and
- NIH funding principles.

The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. NIH policy limits each competitive segment to a maximum of 5 years (exclusive of non-competing extensions). A single award covering the entire period of support generally is used only if the project is solely for construction or modernization of real property, if the total planned period of support will be less than 18 months, or if the project is awarded under a special support mechanism.

The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for compelling programmatic or administrative reasons. The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Recipients are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Report). A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future-year commitments. NIH may decide to withhold support for one or more of the reasons cited in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support. A recipient may appeal this decision only if the withholding was for the recipient's failure to comply with the terms and conditions of a previous award (see Administrative Requirements—Grant Appeals Procedures).

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31 of the fifth fiscal year after the year of availability. This provision may limit the availability of funds for carryover. It may also limit or eliminate the authority to extend the final budget period when an entire project period is funded by a single award (e.g., multiyear funded awards).

5.4 BUDGET

Each NoA sets forth the amount of funds awarded. The amount may be shown either as a categorical (line item) budget or as an amount for total direct costs (not broken down by category) and an amount

for F&A costs, if applicable. Modular awards represent a type of award made without a categorical budget (see Modular Applications and Awards chapter in IIB). The recipient has certain rebudgeting flexibility within the overall amount awarded (see Administrative Requirements—Changes in Project and Budget). The recipient may be required to provide matching funds under construction awards as specified in Construction Grants—Matching in IIB as well as under other NIH programs or awards if specified in the funding opportunity announcement.

5.5 ADDITIONAL TERMS AND CONDITIONS

In addition to, or in lieu of, the standard terms and conditions of award specified in the NIHGPS, NIH may use terms and conditions for program-specific or award-specific reasons. For example, if, on the basis of a recipient's application or other available information, the GMO finds—at the time of award or at any time subsequent to award—that the recipient's management systems and practices are not adequate to ensure the appropriate stewardship of NIH funds or to achieve the objectives of the award, the GMO may impose special, more restrictive terms and conditions on the award in accordance with applicable regulations including 42 CFR Part 52.9 and 2 CFR Part 200.339 and 45 CFR Part 75.371. For example, NIH could require a recipient to obtain prior approval for expenditures that ordinarily do not require such approval or to provide more frequent reports. In addition to closer monitoring, NIH may assist the recipient in taking any necessary corrective action.

6 PAYMENT

The PMS is a centralized grants payment and cash management system, operated by HHS PSC, PMS. HHS grant payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis, as specified in the NoA and as described in this chapter. Payments under NIH grants generally are made as advance payments. NIH grant payments are made by PMS, operated by PSC, in accordance with Department of the Treasury and OMB requirements, as implemented by 2 CFR Part 200.305 and 45 CFR Part 75.305. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal government and disbursement by a recipient. Therefore, although the grant may be financed by advance payments, the intent is that recipients draw funds on an as-needed basis—specifically, no more than 3 business days before the funds are needed.

All Federal funds deposited by PMS in a recipient's bank account as an unrestricted advance payment should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next workday after receipt of the funds. The potential for excessive Federal cash on hand exists each time a recipient does not disburse Federal funds in this manner. The recipient is responsible for determining when the Federal funds have been deposited into its bank account for each drawdown, ensuring that the funds are fully disbursed by the close of business the next workday after they are received, and immediately returning all undisbursed Federal funds to PMS.

The Treasury and OMB policies also establish accountability for interest earned on advances of grant funds and provide for use of the reimbursement method if cash management requirements are not met. Advances made by recipients to consortium participants and contractors under grants must conform to substantially the same standards of timing and amount that govern advances to the recipient.

Operational guidance for recipients is provided through a training CD from PSC. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds through the Federal Financial Report (SF 425) should be directed to PSC/PMS (see Part III).

6.1 SMARTLINK II/ACH

The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to a recipient's bank account and requires recipients to have Internet access to submit a request for funds to PMS. SMARTLINK II/ACH provides funds the day following the request with direct deposit using the Federal Reserve Bank's (Richmond, Virginia) ACH process.

6.2 CASH REQUEST

Recipients not eligible for an unrestricted advance of funds by SMARTLINK II/ACH must submit a cash request, usually monthly. The cash request may be on either an advance or reimbursement basis, as specified by the NIH awarding IC. Cash requests are used when a recipient's cash management must be closely monitored (for example, recipients whose financial management systems do not meet the standards specified in 2 CFR Part 200.302 and 45 CFR Part 75.302) or under programs where reimbursement financing is appropriate. A recipient also may be converted from an unrestricted advance payment method to a cash request basis if, during post-award administration, the GMO determines that a recipient is not complying with the cash management requirements or other requirements of the award, including the submission of complete and timely reports (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Enforcement Actions—Modification of the Terms of Award).

If the cash request is for an advance payment, the recipient may request grant funds from PMS monthly on the basis of expected disbursements during the succeeding month and the amount of Federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, a recipient must submit the request through the awarding IC early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment to the recipient electronically through the ACH process upon receipt of the approved payment request from the awarding IC.

6.3 INTEREST EARNED ON ADVANCES OF GRANT FUNDS

Except as provided in 2 CFR Part 200.305(b)(8) and 45 CFR Part 75.305, any NIH recipient subject to the requirements of 2 CFR Part 200 and 45 CFR Part 75 that receives advance payments must maintain those advances in an interest-bearing account.

Recipients are expected to promptly return any funds not spent within three business days. As provided in 2 CFR Part 200.305(b)(9) and and 45 CFR Part 75.305 subject to the requirements of 2 CFR Part 200 and 45 CFR Part 75 and to the extent required by law, interest earned on Federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to $500 per year may be retained by the non-Federal entity for administrative expense.

6.4 IMPROPER PAYMENTS ELIMINATION AND RECOVERY IMPROVEMENT ACT

The Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (PL 112-248), signed into law on January 10, 2013, established the Do Not Pay Initiative to reduce improper payments or awards. Improper payments occur when funds go to the wrong recipient, the recipient receives the incorrect amount of funds (including overpayments and underpayments), documentation is not available to support a payment, or the recipient uses funds in an improper manner. Incorrect amounts are overpayments or underpayments that are made to eligible recipients (including inappropriate denials of payment or service, any payment that does not account for credit for applicable discounts, payments that are for an incorrect amount, and duplicate payments). When an agency’s review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment should also be considered an improper payment. When establishing documentation requirements for payments, agencies should ensure that

all documentation requirements are necessary and should refrain from imposing additional burdensome documentation requirements. Interest or other fees that may result from an underpayment by an agency are not considered an improper payment if the interest was paid correctly. These payments are generally separate transactions and may be necessary under certain statutory, contractual, administrative, or other legally applicable requirements.

HHS has implemented provisions of IPERIA through integrating use of the Do Not Pay system into the current payment processes managed by the PMS, HHS.

7 COST CONSIDERATION

7.1 GENERAL

Cost considerations are critical throughout the life cycle of a grant. An applicant's budget request is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of recipient and the type of award. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the recipient may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for recipients to deviate from the award budget, depending on the deviation's significance to the project or activity. More significant post-award changes require NIH prior approval. Prior approval requirements and authorities are discussed in Administrative Requirements—Changes in Project and Budget.

During post-award administration, the GMO, or a GMO designee, monitors expenditures for conformance with cost policies. The GMO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports. The GMO also may use audit findings as the basis for final cost adjustments (see Administrative Requirements—Closeout).

This chapter addresses the general principles underlying the allowability of costs, differentiates direct costs from F&A costs, and highlights a number of specific costs and categories of cost for NIH applicants and recipients. It is not intended to be all-inclusive and should be used as a supplement to the applicable cost principles.

7.2 THE COST PRINCIPLES

In general, NIH grant awards provide for reimbursement of actual, allowable costs incurred and are subject to Federal cost principles. The cost principles establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or F&A costs, and set forth allowability and allocability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization (regardless whether domestic or foreign) making the expenditure. For example, a commercial organization collaborating with a university recipient would be subject to the cost principles for commercial organizations, while the university would be subject to the cost principles for Institutions of Higher Educations (IHEs).

The cost principles are set forth in HHS regulations at 2 CFR Part 200, Subpart E, 45 CFR Part 75, Subpart E, and Appendix IX (Hospital Cost Principles) to Part 200 and Part 45. Commercial organizations are subject to the cost principles located at 48 CFR Part 31.2 Federal Acquisition Regulation.

The cost principles apply to all NIH award instruments, award mechanisms, and special programs and authorities, including modular awards and awards under SNAP with one exception: they do not apply to Kirschstein-NRSA individual fellowship awards. The allowable use of funds under those awards is included in Ruth L. Kirschstein National Research Service Awards in IIB.

Recipients may use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as they meet the standards prescribed in 2 CFR Part 200.302 and 45 CFR Part 75.302 for financial management systems.

The cost principles address four tests to determine the allowability of costs. The tests are as follows:

- ***Reasonableness (Including Necessity).*** A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the grant's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large as well as to the organization.
- ***Allocability.*** A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable to a grant if it is incurred solely in order to advance work under the grant; it benefits both the grant and other work of the institution, including other grant-supported projects; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant. A cost is allocable as a direct cost to a grant if it is incurred solely in order to advance work under the grant or meets the criteria for closely related projects determination (see Cost Considerations—Allocation of Costs and Closely Related Work).
- ***Consistency.*** Recipients must be consistent in assigning costs to cost objectives. Costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program, but all costs must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding.
- ***Conformance.*** This test of allowability—conformance with limitations and exclusions as contained in the terms and conditions of award, including those in the cost principles—varies by the type of activity, the type of recipient, and other characteristics of individual awards. Cost Considerations—Allowability of Costs/Activities provides information common to most NIH grants and, where appropriate, specifies some of the distinctions if there is a different treatment based on the type of grant or recipient. IIB contains additional information on allowability of costs for particular types of grants, recipients, and activities.

These four tests apply regardless of whether the particular category of costs is one specified in the cost principles or one governed by other terms and conditions of an award. These tests also apply regardless of treatment as a direct cost or an F&A cost. The fact that a proposed cost is awarded as requested by an applicant does not indicate a determination of allowability.

7.3 DIRECT COSTS AND FACILITIES AND ADMINISTRATIVE COSTS

A direct cost is any cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the grant-supported project or activity. If directly related to a specific award, certain costs that otherwise would be treated as indirect costs may also be considered direct costs. Most organizations also incur costs for common or joint objectives that cannot be readily identified with an individual project or program. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that usually are treated as F&A costs. The organization is responsible for the management and accounting of costs consistently and must not include costs associated with its F&A rate as direct costs.

Note, the term facilities and administrative costs and the term indirect costs may be used interchangeably to determine applicable policies. For NIH purposes, including the NIHGPS, these costs will be referred to as F&A costs; however, other documents or non-NIH entities may refer to them as indirect costs.

Project costs consist of the allowable direct costs directly related to the performance of the grant plus the allocable portion of the allowable F&A costs of the organization, less applicable credits (as described below and in the cost principles).

The amount NIH awards for each budget period will reflect the total approved budget for the grant, including direct costs and, if applicable, F&A costs. (SBIR and STTR awards also may include a fee as specified in Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs in IIB.) If a recipient waives reimbursement of full F&A costs, NIH will either not award F&A costs or will award only partial F&A costs, as appropriate. The NIH award amount shown in the NoA constitutes NIH's maximum financial obligation to the recipient under that award.

7.4 REIMBURSEMENT OF FACILITIES AND ADMINISTRATIVE COSTS

For grant programs that can provide F&A cost reimbursement, NIH will generally not provide F&A costs unless the recipient has established an F&A cost rate covering the applicable activities and period of time, except for awards under which F&A costs are reimbursed at a fixed rate.

In addition, NIH will not require a recipient to establish an F&A rate if the organization's total operations consist of a single grant-supported project or if the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such. In the latter case, the GMO must be satisfied that the organization's accounting system can adequately identify and support all costs as direct costs to the project. This includes being able to identify and segregate costs on the basis of a process that assigns costs commensurate with the benefits provided to individual projects (see Administrative Requirements—Management Systems and Procedures—Financial Management System Standards).

F&A rates are negotiated by CAS, DFAS in the Office of Acquisition Management and Policy, NIH (responsible for negotiating F&A cost rates for commercial entities receiving awards from HHS), or other agency with cognizance for F&A/indirect cost rate (and other special rate) negotiation. If an applicant is advised by the GMO of the need to establish a rate, the GMO will indicate the responsible office to be contacted.

F&A cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant office or agency for indirect costs and must conform to cost policies in the NIHGPS. Further information concerning the establishment of F&A rates and the reimbursement of F&A costs may be obtained from DCA or DFAS (see Part III). CAS should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of 2 CFR Part 200, Subpart E-Cost Principles.

Consistent with 2 CFR Part 200.414(f) and 45 CFR Part 75.414, any institution of higher education (IHE), nonprofit organization, or state or local government that has never received a negotiated indirect cost rate, except for those non-Federal entities described in 2 CFR Part 200, Appendix VII, Section D(1)(b) and 45 CFR Part 75, Appendix VII may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. No documentation is required to justify the 10% de minimis indirect cost rate. As described in 2 CFR Part 200.403 and 45 CFR Part 75.403, costs must be consistently charged as either indirect or direct costs but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal

awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.

If a subrecipient already has a negotiated indirect cost rate established with their cognizant agency for indirect cost, the negotiated rate must be used. If no approved rate exists, the pass-through entity must determine the appropriate rate in collaboration with the subrecipient, which is either: the negotiated indirect cost rate between the pass-through entity and the subrecipient; which can be based on a prior negotiated rate between a different PTE and the same subrecipient. If basing the rate on a previously negotiated rate, the pass-through entity is not required to collect information justifying this rate but may elect to do so; or the de minimis indirect cost rate. The pass-through entity must not require use of a de minimis indirect cost rate if the subrecipient has a Federally approved rate. Subrecipients can elect to use the cost allocation method to account for indirect costs. The cost principles are designed to provide that Federal awards bear their fair share of costs recognized under these principles.(See 2 CFR 200.100(c) and 45 CFR Part 75.100). Pass-through entities may, but are not required, to negotiate a rate with a proposed subrecipient that asks to do so. If the consortium is with a commercial entity, such as a small business, the organization must have an established F&A cost rate before they can charge F&A costs. The default small business rate of 40 percent is only applicable to SBIR and STTR applications.

Regardless of the type of recipient, the rate(s) in effect at the beginning of the competitive segment will be used to determine the amount budgeted for F&A costs for each year of the competitive segment. If the rate agreement does not extend to the end of the project period, the last rate in effect will be used to establish the total cost commitment for any remaining future years. NIH generally will not award additional F&A costs beyond those calculated in the approved budget.

F&A costs awarded may be subject to upward or downward adjustment, depending on the type of rate negotiated and recipient type. Generally, recipients may rebudget between direct and F&A costs (in either direction) without NIH prior approval, provided there is no change in the scope of the approved project. F&A cost reimbursement on grants formerly subject to OMB Circular A-21 (IHEs) is based on the rates used in the award, which are not subject to adjustment in reimbursement except for the establishment of permanent rates when a provisional rate was used for funding. Therefore per 2 CFR 200 Appendix III and 45 CFR Part 75, Appendix III C.7, recipients formerly subject to OMB Circular A-21 (IHEs) may not rebudget from direct costs to accommodate a rate increase if the F&A costs provided for a period were based on negotiated (final, fixed or predetermined) rates rather than provisional rates (defined as not “negotiated” for the application of the OMB Circular A-21 requirement). However, for recipients that were not formerly subject to OMB Circular A-21 (e.g., SBIR/STTR recipients), F&A cost reimbursement is based on the negotiated F&A rate agreement consistent with the time period when the cost is incurred, except if F&A costs were limited or not provided. F&A costs are subject to downward adjustment if the proposal that served as the basis for the negotiation included unallowable costs.

Some grants require negotiation of project costs annually, e.g., clinical trials. For these awards, the policies pertain to each year of support rather than to a multiyear competitive segment.

Once NIH awards a grant, it is not obligated to make any supplemental or other award for additional F&A costs or for any other purpose. There are limited circumstances under which the GMO may award F&A costs where none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for F&A costs because the applicant or recipient did not submit a timely F&A cost proposal and the recipient subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for F&A costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the F&A costs applicable to the period after the date of the recipient’s F&A cost proposal submission. This provision does not affect local governmental agencies that are not required to submit their F&A (indir-

ect) cost proposals to the Federal government. They may charge F&A costs to NIH grants based on the rate computations they prepare and keep on file for subsequent Federal review.

If funds are available, a GMO may amend an award to provide additional funds for F&A costs, but only under the following circumstances:

- NIH made an error in computing the award. This includes situations in which a higher rate than the rate used in the grant award is negotiated and the date of the rate agreement for the higher rate is before 1 calendar month prior to the beginning date of the grant budget period.
- NIH restores funds previously recaptured as part of a recipient's unobligated balance.
- The recipient is eligible for additional F&A costs associated with additional direct costs awarded for the supplementation or extension of a project.

NIH does not reimburse indirect costs under the following classes of awards:

- ***Fellowships.*** F&A costs will not be provided on Kirschstein-NRSA individual fellowships or similar awards for which NIH funding is in the form of fixed amounts or is determined by the normal published tuition rates of an institution and for which the recipient is not required to account on an actual cost basis.
- ***Construction and Modernization.*** F&A costs will not be provided on construction or modernization grants.
- ***Grants to Individuals.*** F&A costs will not be provided on awards to individuals.
- ***Grants to Federal Institutions.*** F&A costs will not be provided on grants to Federal institutions.
- ***Grants in Support of Scientific Meetings (Conference Grants).*** F&A costs will not be provided under grants in support of scientific meetings.
- ***Endowment Grants.*** F&A costs will not be provided for endowment grants.

NIH limits the amounts included in the F&A base for the following type of costs:

- ***Genomic Arrays (GA)*** are a high-throughput genetic analysis technology which enables the study of genetic variation and gene expression at high resolution. Approaches such as genome-wide association and gene expression profiling often depend upon manufactured products known as microarrays or bead arrays. These tools are exceptional among laboratory supplies in that they are almost always procured from a commercial source; have a relatively high unit cost and are often utilized in large numbers. The treatment of the costs for purchase of GA as "supplies" in these specialized award budgets at high levels of usage would result in the application of F&A cost recovery that is disproportionate to the actual administrative burden associated with the relatively high cost of the procurement of these GA. Accordingly, for purposes of budgeting for and award of high volume purchases of GA in excess of $50,000 per year, the standard treatment of these resources as supplies in determining the F&A base of an award will be non-applicable. Instead the requested and reimbursed costs for GA will utilize as a surrogate the concept of subcontracts (consortium/contractual cost). Therefore for each budget year, the first $50,000 of GA will be treated as "supplies", and any GA in excess of $50,000 (for high volume requirements) will use as a surrogate the budgeting and reimbursement concept utilized for subcontracts (consortium/contractual cost), providing consistent budgeting, accounting and reimbursement of these costs.

NIH provides F&A costs without the need for a negotiated rate under the following classes of awards:

- ***Research Training and Education Grants (e.g., R25), and K Awards.*** F&A costs under Kirschstein-NRSA institutional research training grants, educational and K awards will be budgeted and reimbursed at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, expenditures for equipment, and consortiums in excess of $25,000. State, local, and Indian tribes (or "federally recognized Indian tribes") may receive full F&A cost reimbursement under NIH Kirschstein-NRSA institutional research training grants and K awards. For this policy, State universities or hospitals are not considered governmental agencies.
- ***Grants to Foreign Organizations and International Organizations.*** With the exception of the American University of Beirut and the World Health Organization, which are eligible for full F&A cost reimbursement, F&A costs under grants to foreign and international organizations will be funded at a fixed rate of 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. Some examples of NIH compliance requirements are the protection of human subjects (including the required education in the protection of human research participants), animal welfare, invention reporting, other post-award reporting requirements, financial conflict of interest and research misconduct. Note, these are just a few representative examples of compliance requirement; this list is not all inclusive. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. NIH will not support the acquisition of or provide for depreciation on any capital expenses (facilities) or the normal general operations of foreign and international organizations. Therefore, these expenses may not be requested as a direct cost; however, equipment is an allowable direct cost. *Other items normally treated as F&A costs (e.g., rent) may be requested as direct costs and will be evaluated by NIH for allowability.*

7.5 COST TRANSFERS, OVERRUNS, AND ACCELERATED AND DELAYED EXPENDITURES

Cost transfers to NIH grants by recipients, consortium participants, or contractors under grants that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the recipient, consortium participant, or contractor. An explanation merely stating that the transfer was made “to correct error” or “to transfer to correct project” is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.

Recipients must maintain documentation of cost transfers, pursuant to 2 CFR Part 200.337 and 45 CFR Part 75.364, and must make it available for audit or other review (see Administrative Requirements—Monitoring—Record Retention and Access). The recipient should have systems in place to detect such errors within a reasonable time frame; untimely discovery of errors could be an indication of poor internal controls. Frequent errors in recording costs may indicate the need for accounting system improvements, enhanced internal controls, or both. If such errors occur, recipients are encouraged to evaluate the need for improvements and to make whatever improvements are deemed necessary to prevent reoccurrence. NIH also may require a recipient to take corrective action by imposing additional terms and conditions on an award(s).

The GMO monitors recipient expenditure rates under individual grants within each budget period and within the overall project period. The funding that NIH provides for each budget period is based on an assessment of the effort to be performed during that period and the recipient's associated budget, including the availability of unobligated balances. Although NIH allows recipients certain flexibilities with respect to rebudgeting (see Administrative Requirements—Changes in Project and Budget), NIH expects the rate and types of expenditures to be consistent with the approved project and budget and may question or restrict expenditures that appear inconsistent with these expectations.

The GMO may review recipient cash drawdowns to determine whether they indicate any pattern of accelerated or delayed expenditures. Expenditure patterns are of particular concern because they may indicate a deficiency in the recipient's financial management system or internal controls. Accelerated or delayed expenditures may result in a recipient's inability to complete the approved project within the approved budget and period of performance. In these situations, the GMO may seek additional information from the recipient and may make any necessary and appropriate adjustments.

7.6 ALLOCATION OF COSTS AND CLOSELY RELATED WORK

When salaries or other activities are supported by two or more sources, issues arise as to how the direct costs should be allocated among the sources of support. In general, a cost that benefits two or more projects or activities in proportions that can be determined without undue effort or cost should be allocated to the projects on the basis of the proportional benefit. A cost that benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved may be allocated or transferred to the benefiting projects on any reasonable basis as long as the costs charged are allowable, allocable, and reasonable under the applicable cost principles and the recipient's financial management system includes adequate internal controls (for example, no one person has complete control over all aspects of a financial transaction).

7.7 APPLICABLE CREDITS

The term applicable credits refers to those receipt or negative expenditure types of transactions that operate to offset or reduce direct or F&A cost items. Typical examples are purchase discounts, rebates or allowances, recoveries or indemnities on losses, and adjustments for overpayments or erroneous charges. Additional information concerning applicable credits is included in the cost principles.

Applicable credits to direct charges made to NIH grants must be treated as an adjustment on the recipient's FFR, whether those credits accrue during or after the period of grant support. (See Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout—Final Federal Financial Reports.) The NIH awarding IC will notify the recipient of any additional actions that may be necessary.

7.8 SERVICES PROVIDED BY AFFILIATED ORGANIZATIONS

A number of universities and other organizations have established closely affiliated, but separately incorporated, organizations to facilitate the administration of research and other programs supported by Federal funds. Such legally independent entities are often referred to as "foundations," although this term does not necessarily appear in the name of the organization. Sometimes, the parent organization provides considerable support services, in the form of administration, facilities, equipment, accounting, and other services, to its foundation, and the latter, acting in its own right as an NIH recipient, includes the cost of these services in its F&A proposal.

Costs incurred by an affiliated, but separate, legal entity in support of a recipient foundation are allowable for reimbursement under NIH grants only if at least one of the following conditions is met:

- The affiliated organization is charged for, and is legally obligated to pay for, the services provided by the parent organization.
- The affiliated organizations are subject to State or local law that prescribes how Federal reimbursement for the costs of the parent organization's services will be expended and requires that a State or local official acting in their official capacity approves such expenditures.
- There is a valid written agreement between the affiliated organizations whereby the parent organization agrees that the recipient foundation may retain Federal reimbursement of parent organization costs. The parent organization may either direct how the funds will be used or permit the recipient foundation that discretion.

If none of the above conditions are met, the costs of the services provided by the parent organization to the recipient foundation are not allowable for reimbursement under an NIH grant. However, the services may be acceptable for cost-sharing (matching) purposes.

Foundations that represent already existing recipient organizations should contact DGP, OPERA before attempting to become a separately recognized applicant organization.

7.9 ALLOWABILITY OF COSTS/ACTIVITIES

The governing cost principles address selected items of cost, some of which are mentioned in this section for emphasis. This section is not intended to be all-inclusive. The cost principles should be consulted for the complete explanation of whether or not a cost is allowed.

This section also includes NIH-specific requirements concerning costs and activities. The allowability of costs under specific NIH awards may be subject to other requirements specified in the program legislation, regulations, or the specific terms and conditions of an award, which take precedence over the general discussion provided here. Specific program requirement may also be covered in other sections of the NIH GPS. Applicants or recipients that have questions concerning the allowability of particular costs should contact the GMO.

If a cost is allowable, it is allocable as either a direct cost or an F&A cost, depending on the recipient's accounting system. For some costs addressed in this section, the text specifies whether the cost is usually a direct cost or an F&A cost.

Unless otherwise indicated in the NoA, an award based on an application that includes specific information concerning any costs or activities that require NIH prior approval constitutes the prior approval for those costs or activities. The recipient is not required to obtain any additional approval for those costs/activities. Post-award requests to incur costs or undertake activities requiring prior approval that are not described in the approved application are subject to the requirements in Administrative Requirements—Changes in Project and Budget.

Consortium participants and contractors under grants are subject to the requirements of the cost principles otherwise applicable to their type of organization and to any requirements placed on them by the recipient to be able to comply with the terms and conditions of the NIH grant.

The cost principles do not address profit or fee. NIH policy allows the payment of fee on SBIR/STTR grants (see Grants to For-Profit Organizations chapter in IIB) but NIH will not provide profit or fee to any other type of recipient under any other grant program or support mechanism. A fee may not be paid by a recipient to a consortium participant, including a commercial organization. However, a fee (profit)

may be paid to a contractor providing routine goods or services under a grant in accordance with normal commercial practice.

7.9.1 Selected Items of Cost

Exhibit 5: Selected Items of Cost

The table presents specific items that may or may not be included in the cost portion of grants

Items	Explanation of Allowable Costs
Advertising and Public Relations	1. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television, direct mail, exhibits, electronic or computer transmittals, and the like. 2. The only allowable advertising costs are those which are solely for: a. The recruitment of personnel required by the non-Federal entity for performance of a Federal award (See also 2 CFR Part 200.463 and 45 CFR Part 75.463); b. The procurement of goods and services for the performance of a Federal award; c. The disposal of scrap or surplus materials acquired in the performance of a Federal award except when non-Federal entities are reimbursed for disposal costs at a predetermined amount; or d. Program outreach and other specific purposes necessary to meet the requirements of the Federal award. 3. The term ‘‘public relations’’ includes community relations and means those activities dedicated to maintaining the image of the non- Federal entity or maintaining or relations with the community or public at large or any segment of the public. 4. The only allowable public relations costs are: a. Costs specifically required by the Federal award; b. Costs of communicating with the public and press pertaining to specific activities or accomplishments which result from performance of the Federal award (these costs are considered necessary as part of the outreach effort for the Federal award); or c. Costs of conducting general liaison with news media and government public relations officers, to the extent that such activities are limited to communication and liaison necessary to keep the public informed on matters of public concern, such as notices of funding opportunities, financial matters, etc. 5. Unallowable advertising and public relations costs include the following: a. All advertising and public relations costs other than as specified in paragraphs (2) and (4) of this section; b. Costs of meetings, conventions, convocations, or other events related to other activities of the entity (see also 2 CFR Part 200.432 and 45 CFR Part 75.432), including: i. Costs of displays, demonstrations, and exhibits; ii. Costs of meeting rooms, hospitality suites, and other special facilities used in conjunction with shows and other special events; and

Items	Explanation of Allowable Costs
	iii. Salaries and wages of employees engaged in setting up and displaying exhibits, making demonstrations, and providing briefings; c. Costs of promotional items and memorabilia, including models, gifts, and souvenirs; d. Costs of advertising and public relations designed solely to promote the non-Federal entity
Alcoholic Beverages	Unallowable as an entertainment expense, but allowable if within the scope of an approved research project.
Alteration and Renovation	Individual A&R projects that are treated as direct costs and that are determined to be minor be subject to the A&R policies specified in this exhibit and in the Construction Grants chapter, as applicable. Individual A&R projects determined to be A&R will be subject to the requirements specified in the Construction Grants chapter. Routine maintenance and repair of the organization's physical plant or equipment, which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this policy. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, may be considered either equipment costs or A&R costs, depending on the recipient's accounting system. A&R costs are not allowable under grants to individuals, and grants in support of scientific meetings (conference grants). In all other cases, these costs are allowable unless the program legislation, implementing regulations, program guidelines, or other terms and conditions of the award specifically exclude such activity. The A&R must be consistent with the following criteria and documentation requirements: • The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required. • The A&R is essential to the purpose of the grant-supported project. • The space involved will be occupied by the project. • The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage. • If the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the project period.

Items	Explanation of Allowable Costs
	• If the A&R will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the requirements specified in "Preservation of Cultural and Historic Resources" have been followed. Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost. A recipient may rebudget up to 25 percent of the total approved budget for a budget period into A&R costs without NIH prior approval unless such rebudgeting would result in a change in scope. If the rebudgeting will result in the addition of a major A&R project, NIH will consider the rebudgeting to be a change in scope, and the recipient must submit to the NIH awarding IC the documentation specified in the Construction Grants chapter for prior approval of A&R projects above that dollar level. Under foreign grants or foreign components under domestic grants, major A&R is unallowable. Minor A&R is generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations.
Animals	Allowable for the acquisition, care, and use of experimental animals, contingent upon compliance with the applicable requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (see Public Policy Requirements and Objectives—Animal Welfare). If the recipient operates an animal resource facility, charges for use of the facility should be determined in accordance with the *Cost Analysis and Rate Setting Manual for Animal Resource Facilities* (PDF, 32 MB) - May 2000.
Audiovisual Activities	Allowable for the production of an audiovisual. "Audiovisual" means any product containing visual imagery, sound, or both, such as motion pictures, films, videotapes, live or recorded radio or television programs or public service announcements, slide shows, filmstrips, audio recordings, multimedia presentations, or exhibits where visual imagery, sound, or both are an integral part. "Production" refers to the steps and techniques used to create a finished audiovisual product including, but not limited to, design, layout, scriptwriting, filming or taping, fabrication, sound recording, and editing. A recipient with in-house production capability must determine whether it would be more efficient and economical to use that capability or to contract for the production of an audiovisual. If an audiovisual intended for members of the general public (i.e., people who are not researchers or health professions personnel or who are not directly involved in project activities as employees, trainees, or participants such as volunteers or patients) is produced under an NIH grant-supported project, the recipient must submit two copies of the finished product along with its annual or final progress report (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout). The costs of such copies are allowable project costs. Audiovisuals produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, such as the following:

Items	Explanation of Allowable Costs
	The production of this [type of audiovisual (motion picture, television program, etc.)] was supported by Grant No._____ from [name of NIH awarding IC]. Its contents are solely the responsibility of [name of recipient organization] and do not necessarily represent the official views of [name of NIH awarding IC].
Audit Services	1. A reasonably proportionate share of the costs of audits required by, and performed in accordance with, the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507), as implemented by requirements of 2 CFR Part 200, are allowable. However, the following audit costs are unallowable: a. Any costs when audits required by the Single Audit Act and Subpart F— Audit Requirements of 2 CFR Part 200 and 45 CFR Part 75, Subpart F have not been conducted or have been conducted but not in accordance therewith; and b. Any costs of auditing a non- Federal entity that is exempted from having an audit conducted under the Single Audit Act and Subpart F—Audit Requirements of 2 CFR Part 200, and 45 CFR Part 75, Subpart F because its expenditures under Federal awards are less than $750,000 during the non- Federal entity's fiscal year. 2. The costs of a financial statement audit of a non-Federal entity that does not currently have a Federal award may be included in the indirect cost pool for a cost allocation plan or indirect cost proposal. 3. Pass-through entities may charge Federal awards for the cost of agreed-upon-procedures engagements to monitor subrecipients (in accordance with Subpart D of 2 CFR Part 200.331 through 200.333 and 45 CFR Part 75.351 and 45 CFR Part 75.353) which are exempted from the requirements of the Single Audit Act and Subpart F of 2 CFR Part 200 and 45 CFR Part 75, Subpart F. This cost is allowable only if the agreed-upon-procedures engagements are: a. Conducted in accordance with GAGAS attestation standards; b. Paid for and arranged by the pass-through entity; and c. Limited in scope to one or more of the following types of compliance requirements: activities allowed or unallowed; allowable costs/cost principles; eligibility; and reporting.
Bad Debts	Bad debts (debts which have been determined to be uncollectable), including losses (whether actual or estimated) arising from uncollectable accounts and other claims, are unallowable. Related collection costs, and related legal costs, arising from such debts after they have been determined to be uncollectable are also unallowable. (See also 2 CFR Part 200.428 and 45 CFR Part 75.428).

Items	Explanation of Allowable Costs
Bonding	1. Bonding costs arise when the Federal awarding agency requires assurance against financial loss to itself or others by reason of the act or default of the non-Federal entity. They arise also in instances where the non-Federal entity requires similar assurance, including: bonds as bid, performance, payment, advance payment, infringement, and fidelity bonds for employees and officials. 2. Costs of bonding required pursuant to the terms and conditions of the Federal award are allowable. 3. Costs of bonding required by the non-Federal entity in the general conduct of its operations are allowable as an indirect cost to the extent that such bonding is in accordance with sound business practice and the rates and premiums are reasonable under the circumstances.
Books and Journals	Allowable. If an organization has a library, books and journals generally should be provided as part of normal library services and treated as F&A costs.
Building Acquisition	Unallowable unless building acquisition or construction is specifically authorized by program legislation and is provided for in the NoA. For real property acquired with NIH grant support, the cost of title insurance may be charged to the grant in proportion to the Federal share of the acquisition cost. Filing fees for recording the Federal interest in the real property in appropriate records of the applicable jurisdiction also may be charged to the grant. (Also see Construction Grants—Allowable and Unallowable Costs and Activities in IIB).
Capital Expenditures	See Equipment and Other Capital Expenditures.
Child care Costs	Allowable if incurred to assist individuals to participate as subjects in research projects. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see Fringe Benefits and Travel Costs in this exhibit). NRSA Fellowship Grants may also be allowed to incur these costs (see 11.2.9.6 for specific eligibility criteria).
Collection of Improper Payments	The costs incurred by a non-Federal entity to recover improper payments are allowable as either direct or indirect costs, as appropriate. Amounts collected may be used by the non-Federal entity in accordance with cash management standards set forth in 2 CFR Part 200.305 and 45 CFR Part 75.305. (See Improper Payment).
Communications	Allowable. Such costs include local and long-distance telephone calls, express mail, and postage, and usually are treated as F&A costs.
Conference Grant Costs	See Support of Scientific Meetings (Conference Grants) chapter in IIB for allowability of costs for scientific meetings (conferences).
Consortium Agreements/ Contracts under Grants	Allowable to carry out a portion of the programmatic effort or for the acquisition of routine goods or services under the grant. Such arrangements may require NIH approval as specified in Administrative Requirements—Changes in Project and Budget. (See also Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for policies that apply to the acquisition of routine goods and services and the Consortium

Items	Explanation of Allowable Costs
	Agreements chapter in IIB for policies that apply to recipient collaboration with other organizations in carrying out the grant-supported research).
Construction	Allowable only when program legislation specifically authorizes new construction, modernization, or major A&R, and NIH specifically authorizes such costs in the NoA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy (see Construction Grants chapter in IIB).
Consultant Services	See Professional Services and Salaries and Wages/Intra-IHE Consulting.
Contingency Provisions	Unallowable. Payments made by the NIH awarding IC to the non-Federal entity's "contingency reserve" or any similar payment made for events the occurrence of which cannot be foretold with certainty as to the time or intensity, or with an assurance of their happening, are unallowable under non-construction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see Reserve Funds in this exhibit). (See also Construction Grants—Allowable and Unallowable Costs and Activities in IIB concerning contingency funds under construction grants).
Customs and Import Duties	Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (See Taxes in this exhibit).
Depreciation or Use Allowances	Allowable. Such costs usually are treated as F&A costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable.
Donor Costs	Allowable as payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related. Donor costs are not considered a research patient care expense (see the Research Patient Care Costs chapter in IIB). Also see Incentive Costs in this exhibit.
Drugs	Allowable if within the scope of an approved research project. Project funds may not be used to purchase drugs classified by FDA as "ineffective" or "possibly effective" except in approved clinical research projects or in cases where there is no alternative other than therapy with "possibly effective" drugs.
Dues or Membership Fees	Allowable as an F&A cost for organizational membership in business, professional, or technical organizations or societies. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds.

Items	Explanation of Allowable Costs
	See also Membership, Subscription, and Professional Activity costs.
Entertainment Costs	Costs of entertainment, including amusement, diversion, and social activities and any associated costs are unallowable, except where specific costs that might otherwise be considered entertainment have a programmatic purpose and are authorized either in the approved budget for the Federal award or with prior written approval of the NIH awarding IC.
Equipment and Other Capital Expenditures	The following rules of allowability must apply to equipment and other capital expenditures: 1. Capital expenditures for general purpose equipment, buildings, and land are unallowable as direct charges, except with the prior written approval of the NIH awarding IC or pass-through entity. 2. Capital expenditures for special purpose equipment are allowable as direct costs, provided that items that relate to a change in scope (which may be indicated by a unit cost of $25,000 or more) have the prior written approval of the NIH awarding IC or pass-through entity. 3. Capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life are unallowable as a direct cost except with the prior written approval of the NIH awarding IC, or pass-through entity. See Depreciation for rules on the allowability of depreciation on buildings, capital improvements, and equipment. See also Rental Costs of Real Property and Equipment. 4. When approved as a direct charge pursuant to items (1) through (3) above, capital expenditures will be charged in the period in which the expenditure is incurred, or as otherwise determined appropriate and negotiated with the NIH awarding IC. 5. The unamortized portion of any equipment written off as a result of a change in capitalization levels may be recovered by continuing to claim the otherwise allowable depreciation on the equipment, or by amortizing the amount to be written off over a period of years negotiated with the Federal cognizant agency for indirect cost. 6. Cost of equipment disposal. If the non-Federal entity is instructed by the NIH awarding IC to otherwise dispose of or transfer the equipment the costs of such disposal or transfer are allowable. See also Capital Expenditures, Equipment, Special Purpose Equipment, General Purpose Equipment, Acquisition Cost, and Capital Assets.
Federal (U.S. Government) Employees	See Grants to Federal Institutions and Payments to Federal Employees under Grants—Allowable and Unallowable Costs in IIB for the allowability of payments made to, or on behalf of, Federal employees under NIH grants, including grants to Federal institutions.
Fines, Penalties, Damages and Other Settlements	Costs resulting from non-Federal entity violations of, alleged violations of, or failure to comply with, Federal, state, tribal, local or foreign laws and regulations are unallowable, except when incurred as a result of compliance with specific

Items	Explanation of Allowable Costs
	provisions of the Federal award, or with prior written approval of the NIH awarding IC.
Fringe Benefits	Fringe benefits are allowances and services provided by employers to their employees as compensation in addition to regular salaries and wages. Fringe benefits include, but are not limited to, the costs of leave (vacation, family related, sick or military), employee insurance, pensions, and unemployment benefit plans. Except as provided elsewhere in 2 CFR Part 200, Subpart E, the costs of fringe benefits are allowable provided that the benefits are reasonable and are required by law, non-Federal entity-employee agreement, or an established policy of the non-Federal entity. For policies applicable to tuition remission for students working on grant-supported research projects, see Fringe Benefits / IHE Tuition/Tuition Remission in this exhibit. See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Allowable and Unallowable Costs—Tuition and Fees and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs—Trainee Tuition and Fees in IIB for the allowability of tuition costs for fellows and trainees.
Fringe Benefits / IHE *Tuition/Tuition Remission*	Tuition remission and other forms of compensation paid as, or in lieu of, wages to students under research grants are allowable, provided the following conditions are met: 1. The individual is conducting activities necessary to the Federal award. 2. Tuition remission and other support are provided, in accordance with established institutional policy, of the IHE and consistently provided in a like manner to students in return for similar activities conducted under Federal awards as well as other activities. 3. During the academic period, the student is enrolled in an advanced degree program at a non-Federal entity or affiliated institution and the activities of the student in relation to the Federal award are related to the degree program. 4. The tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work. 5. It is the IHE's practice to similarly compensate students under Federal awards as well as other activities Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages are subject to reporting requirements in 2 CFR Part 200.430(i) and 45 CFR Part 75.430. NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of 2 CFR Part 200, Subpart E and 45 CFR Part 75, Subpart E and its current operating guidelines. The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is the zero-level Kirschstein-NRSA stipend in effect when NIH issues the grant award (see current levels posted at

Items	Explanation of Allowable Costs
	http://grants.nih.gov/training/nrsa.htm). Payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project.
Fringe Benefits / Insurance	Allowable. Insurance usually is treated as an F&A cost. In certain situations, however, where special insurance is required as a condition of the grant because of risks peculiar to the project, the premium may be charged as a direct cost if doing so is consistent with organizational policy. Medical liability (malpractice) insurance is an allowable cost of research programs at all types of recipients only if the research involves human subjects. If so, the insurance must be treated as a direct cost and must be assigned to individual grants based on the manner in which the insurer allocates the risk to the population covered by the insurance. See also Reserve Funds. The cost of insuring equipment, whether purchased with project funds or furnished as federally owned property, normally should be included in F&A costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy. Health insurance for trainees and fellows is addressed in the Ruth L. Kirschstein National Research Service Awards chapter in IIB.
Fringe Benefits / Pension Plan Costs	Pension plan costs which are incurred in accordance with the established policies of the non- Federal entity are allowable, provided that: 1. Such policies meet the test of reasonableness. 2. The methods of cost allocation are not discriminatory. 3. For entities using accrual based accounting, the cost assigned to each fiscal year is determined in accordance with GAAP. 4. The costs assigned to a given fiscal year are funded for all plan participants within six months after the end of that year. However, increases to normal and past service pension costs caused by a delay in funding the actuarial liability beyond 30 calendar days after each quarter of the year to which such costs are assignable are unallowable. Non-Federal entity may elect to follow the ‘‘Cost Accounting Standard for Composition and Measurement of Pension Costs’’ (48 CFR Part 9904.412). 5. Pension plan termination insurance premiums paid pursuant to the Employee Retirement Income Security Act (ERISA) of 1974 (29 U.S.C. 1301–1461) are allowable. Late payment charges on such premiums are unallowable. Excise taxes on accumulated funding deficiencies and other penalties imposed under ERISA are unallowable. 6. Pension plan costs may be computed using a pay-as-you-go method or an acceptable actuarial cost method in accordance with established written policies of the non-Federal entity.

Items	Explanation of Allowable Costs
	a. For pension plans financed on a pay-as-you-go method, allowable costs will be limited to those representing actual payments to retirees or their beneficiaries. b. Pension costs calculated using an actuarial cost-based method recognized by GAAP are allowable for a given fiscal year if they are funded for that year within six months after the end of that year. Costs funded after the six month period (or a later period agreed to by the cognizant agency for indirect costs) are allowable in the year funded. The cognizant agency for indirect costs may agree to an extension of the six month period if an appropriate adjustment is made to compensate for the timing of the charges to the Federal government and related Federal reimbursement and the non-Federal entity's contribution to the pension fund. Adjustments may be made by cash refund or other equitable procedures to compensate the Federal government for the time value of Federal reimbursements in excess of contributions to the pension fund. c. Amounts funded by the non- Federal entity in excess of the actuarially determined amount for a fiscal year may be used as the non- Federal entity's contribution in future periods. d. When a non-Federal entity converts to an acceptable actuarial cost method, as defined by GAAP, and funds pension costs in accordance with this method, the unfunded liability at the time of conversion is allowable if amortized over a period of years in accordance with GAAP. e. The Federal government must receive an equitable share of any previously allowed pension costs (including earnings thereon) which revert or inure to the non-Federal entity in the form of a refund, withdrawal, or other credit.
Fringe Benefits / *Severance Pay*	1. Severance pay, also commonly referred to as dismissal wages, is a payment in addition to regular salaries and wages, by non-Federal entities to workers whose employment is being terminated. Costs of severance pay are allowable only to the extent that in each case, it is required by: a. law, b. employer-employee agreement, c. established policy that constitutes, in effect, an implied agreement on the non- Federal entity's part, or d. circumstances of the particular employment. 2. Costs of severance payments are divided into two categories as follows:

Items	Explanation of Allowable Costs
	a. Actual normal turnover severance payments must be allocated to all activities; or, where the non-Federal entity provides for a reserve for normal severances, such method will be acceptable if the charge to current operations is reasonable in light of payments actually made for normal severances over a representative past period, and if amounts charged are allocated to all activities of the non- Federal entity. b. Measurement of costs of abnormal or mass severance pay by means of an accrual will not achieve equity to both parties. Thus, accruals for this purpose are not allowable. However, the Federal government recognizes its obligation to participate, to the extent of its fair share, in any specific payment. Prior approval by the Federal awarding agency or cognizant agency for indirect cost, as appropriate, is required. 3. Costs incurred in certain severance pay packages which are in an amount in excess of the normal severance pay paid by the non-Federal entity to an employee upon termination of employment and are paid to the employee contingent upon a change in management control over, or ownership of, the non-Federal entity's assets, are unallowable. 4. Severance payments to foreign nationals employed by the non-Federal entity outside the United States, to the extent that the amount exceeds the customary or prevailing practices for the non-Federal entity in the United States, are unallowable, unless they are necessary for the performance of Federal programs and approved by the NIH awarding IC. 5. Severance payments to foreign nationals employed by the non-Federal entity outside the United States due to the termination of the foreign national as a result of the closing of, or curtailment of activities by, the non-Federal entity in that country, are unallowable, unless they are necessary for the performance of Federal programs and approved by the NIH awarding IC.
Fundraising and Investment Management Costs	1. Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred to raise capital or obtain contributions are unallowable. Fund raising costs for the purposes of meeting the Federal program objectives are allowable with prior written approval from the Federal awarding agency. (See also Proposal Costs). 2. Costs of investment counsel and staff and similar expenses incurred to enhance income from investments are unallowable except when associated with investments covering pension, self-insurance, or other funds which include Federal participation allowed by 2 CFR Part 200. 3. Costs related to the physical custody and control of monies and securities are allowable.

Items	Explanation of Allowable Costs
	4. Both allowable and unallowable fund raising and investment activities must be allocated as an appropriate share of indirect costs under the conditions described in 2 CFR Part 200.413 and 45 CFR Part 75.413.
Genomic Arrays	Allowable as a direct cost, but with specialized treatment of F&A reimbursement for costs exceeding $50,000 in each budget year. See Cost Considerations-Reimbursement of Facilities and Administrative Costs for more information.
Hazardous Waste Disposal	Allowable; usually treated as an F&A cost.
Honoraria	Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable.
Hospitalization	See Research Patient Care in this exhibit.
Incentive Costs	Incentive payments to volunteers or patients participating in a grant-supported project or program are allowable. Incentive payments to individuals to motivate them to take advantage of grant-supported health care or other services are allowable if within the scope of an approved project. See Salaries and Wages/Incentive Compensation in this exhibit for incentive payments to employees.
Indemnification	Absent express statutory authority, unallowable if the indemnification would result in liability that is indefinite, indeterminate or potentially unlimited. In those rare cases where authority does allow this cost, it would be reflected in the NoA.
Independent Research and Development Costs	Independent research and development is research and development which is conducted by an organization, and which is not sponsored by Federal or non-Federal awards, contracts, or other agreements. Independent research and development shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development. The cost of independent research and development, including their proportionate share of indirect costs, are unallowable.
Intellectual Property (Invention, Copyright, Patent, or Licensing Costs)	Unallowable as a direct cost unless specifically authorized on the grant award. May be allowable as F&A costs, provided they are in accordance with 2 CFR Part 200.448 and 45 CFR Part 75.448 and are included in the negotiation of F&A cost rates.
Interest	Allowable as an F&A cost for certain assets as specified in 2 CFR Part 200.449 and 45 CFR Part 75.449. Unallowable for hospitals. (2 CFR Part 200, Appendix IX, I.o.). (See Payment—Interest Earned on Advances of Grant Funds).
IRB or IACUC Costs	Costs associated with IRB review of human research protocols, or IACUC review of animal research protocols, are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.
Laboratory Directed Research &	NIH awards to DOE laboratories will not include the proportionate share of F&A costs for Laboratory Directed Research & Development (LDRD) in accordance

Items	Explanation of Allowable Costs
Development	with the MOU with the Department of Energy dated June 18, 1998, although NIH will not restrict the DOE laboratory contractors from recovering LDRD costs within the total funding included in an award. In addition, DOE has agreed to waive the Overhead Rate on all NIH grant awards to DOE laboratory contractors.
Leave	Allowable for employees as a fringe benefit (see Fringe Benefits in this exhibit). See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Other Terms and Conditions—Leave and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Other Terms and Conditions—Leave in IIB for NIH policy on leave for fellows and trainees.
Legal Services	Allowable. Generally treated as an F&A cost but, subject to the limitations described in the applicable cost principles, may be treated as a direct cost for legal services provided by individuals who are not employees of the recipient organization. Before a recipient incurs legal costs that are extraordinary or unusual in nature, the recipient should make an advance agreement regarding the appropriateness and reasonableness of such costs with the GMO. Legal costs incurred in defending or prosecuting claims, whether equitable or monetary, including administrative grant appeals, are generally unallowable charges to NIH grant-supported projects, except as expressly permitted in the 2 CFR Part 200.
Library Services	General library support is not allowable as a direct cost but may be included in the recipient's F&A pool. However, such services are allowable as a direct cost when specifically required for the conduct of the project and when identifiable as an integral part of the grant-supported activity (e.g., in those programs designed to develop and support such services).
Lobbying	Generally unallowable, in accordance with 2 CFR Part 200.450 and 45 CFR Part 75.450, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a State legislature. Under certain circumstances, costs associated with activities that might otherwise be considered "lobbying" that are directly related to the performance of a grant may be allowable. The recipient should obtain an advance understanding with the GMO if it intends to engage in these activities. Unallowable for State and Local governments and commercial organizations. (Also see Public Policy Requirements and Objectives—Lobbying Prohibition, Appropriation Mandates – Lobbying – Appropriation Prohibition, and Administrative Requirements—Monitoring—Reporting concerning lobbying restrictions, the required certification, and reporting).
Maintenance and Repair Costs	Costs incurred for utilities, insurance, security, necessary maintenance, janitorial services, repair, or upkeep of buildings and equipment (including Federal property unless otherwise provided for) which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are allowable. Costs incurred for improvements which add to the permanent value of the buildings and equipment or appreciably prolong their intended life must be treated as capital expenditures (see 2 CFR

Items	Explanation of Allowable Costs
	Part 200.439 and 45 CFR Part 75.439). These costs are only allowable to the extent not paid through rental or other agreements.
Materials and Supplies Costs, including Costs of Computing Devices.	1. Costs incurred for materials, supplies, and fabricated parts necessary to carry out a Federal award are allowable. 2. Purchased materials and supplies must be charged at their actual prices, net of applicable credits. Withdrawals from general stores or stockrooms should be charged at their actual net cost under any recognized method of pricing inventory withdrawals, consistently applied. Incoming transportation charges are a proper part of materials and supplies costs. 3. Materials and supplies used for the performance of a Federal award may be charged as direct costs. In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award. 4. Where federally-donated or furnished materials are used in performing the Federal award, such materials will be used without charge.
Meals	Allowable for subjects and patients under study, or where specifically approved as part of the project activity, provided that such charges are not duplicated in participants' per diem or subsistence allowances, if any. When certain meals are an integral and necessary part of a meeting or conference (i.e., a working meal where business is transacted), grant funds may be used for such meals only when consistent with terms of award. The cost of meals served at a meeting or conference, for which the primary purpose is the dissemination of technical information, is no longer allowable on NIH grants where the primary purpose of the grant is to support a conference or meeting (see also Support of Scientific Meetings (Conference Grants) Section 14.10.1). However, when such a meeting/conference is an ancillary effort under a grant where the primary purpose is other than to support such a meeting/conference, then the cost of meals would be allowable. When allowable as a direct charge, the cost of any meal must meet a test of reasonableness. However, recurring business meetings, such as staff meetings, should not be broadly considered as meetings for the primary purpose of disseminating technical information in order to justify charging meals or refreshment costs to grants.
Membership, Subscription, and Professional Activity Costs	1. Costs of the non-Federal entity's membership in business, technical, and professional organizations are allowable as an F&A cost. 2. Costs of the non-Federal entity's subscriptions to business, professional, and technical periodicals are allowable. 3. Costs of membership in any civic or community organization are allowable with prior approval by the NIH awarding IC or pass-through entity.

Items	Explanation of Allowable Costs
	4. Costs of membership in any country club or social or dining club or organization are unallowable. 5. Costs of membership in organizations whose primary purpose is lobbying are unallowable. See also Lobbying. 6. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds.
Moving	See Recruitment Costs, Relocation Costs, and Transportation Costs in this exhibit.
Nursery Items	Allowable for the purchase of items such as toys and games to allow patients to participate in research protocols.
Overtime	See Salaries and Wages/Extra Service Pay (Overtime) in this exhibit.
Participant Support Costs	Only allowable when identified in specific FOAs.
Pre-Award (Pre-Agreement) Costs	Allowable. A recipient may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs: • are necessary to conduct the project, and • would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award. Pre-award costs must be charged to the initial budget period of the award, unless otherwise specified by NIH. Recipients may incur pre-award costs before the beginning date of a non-competing continuation award without regard to the time parameters stated above. The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the recipient's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. Pre-Award Costs are generally not applicable to training grants or fellowships. See respective sections for Individual Fellowships and Institutional Training

Items	Explanation of Allowable Costs
	Grants in the Ruth L. Kirschstein National Research Service Award chapter in IIB for additional information.
Professional Services Costs	1. Costs of professional and consultant services rendered by persons who are members of a particular profession or possess a special skill, and who are not officers or employees of the non-Federal entity, are allowable, subject to paragraphs (b) and (c) below when reasonable in relation to the services rendered and when not contingent upon recovery of the costs from the Federal government. In addition, legal and related services are limited under 2 CFR Part 200.435 and 45 CFR Part 75.435. 2. In determining the allowability of costs in a particular case, no single factor or any special combination of factors is necessarily determinative. However, the following factors are relevant: a. The nature and scope of the service rendered in relation to the service required. b. The necessity of contracting for the service, considering the non-Federal entity's capability in the particular area. c. The past pattern of such costs, particularly in the years prior to Federal awards. d. The impact of Federal awards on the non-Federal entity's business (i.e., what new problems have arisen). e. Whether the proportion of Federal work to the non-Federal entity's total business is such as to influence the non- Federal entity in favor of incurring the cost, particularly where the services rendered are not of a continuing nature and have little relationship to work under Federal awards. f. Whether the service can be performed more economically by direct employment rather than contracting. g. The qualifications of the individual or concern rendering the service and the customary fees charged, especially on non-federally funded activities. h. Adequacy of the contractual agreement for the service (e.g., description of the service, estimate of time required, rate of compensation, and termination provisions). 3. In addition to the factors in paragraph (b) above, to be allowable, retainer fees must be supported by evidence of bona fide services available or rendered. Recipients, consortium participants, and contractors under grants are encouraged to obtain written reports from consultants unless such a report is not feasible given the nature of the consultation or would not be useful. Documentation maintained by the receiving organization should include the name of the consulting firm or individual consultant; the nature of the services rendered and their relevance to the grant-supported activities, if not otherwise

Items	Explanation of Allowable Costs
	apparent from the nature of the services; the period of service; the basis for calculating the fee paid (e.g., rate per day or hour worked or rate per unit of service rendered); and the amount paid. This information may be included in the consultant's invoice, in the report, or in another document. See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter in IIB for allowable costs associated with consultant payments to Federal employees and the circumstances of allowability. See Salaries and Wages/Intra-IHE Consulting.
Profit or Fee	Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a commercial organization, whether as a recipient or as a consortium participant. A profit or fee under a grant is not a cost, but is an amount in excess of actual allowable direct and F&A costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an NIH grant providing routine goods or services to the recipient.
Proposal Costs	Proposal costs are the costs of preparing bids, proposals, or applications on potential Federal and non-Federal awards or projects, including the development of data necessary to support the non-Federal entity's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect (F&A) costs and allocated currently to all activities of the non- Federal entity. No proposal costs of past accounting periods will be allocable to the current period.
Public Relations Costs	See Advertising and Public Relations.
Publication and Printing Costs	1. Publication costs for electronic and print media, including distribution, promotion, and general handling are allowable. If these costs are not identifiable with a particular cost objective, they should be allocated as indirect costs to all benefiting activities of the non-Federal entity. 2. Page charges for professional journal publications are allowable where: a. The publications report work supported by the Federal government; and b. The charges are levied impartially on all items published by the journal, whether or not under a Federal award. If charged to the award, these costs must be charged to the final budget period of the award, unless otherwise specified by NIH c. The non-Federal entity may charge the Federal award before closeout for the costs of publication or sharing of research results if the costs are not incurred during the period of performance of the Federal award. Publications and journal articles produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, as appropriate, as provided in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

Items	Explanation of Allowable Costs
Rearrangement and Reconversion Costs	See Alteration and Renovation costs.
Recruiting Costs	1. Subject to paragraphs (2) and (3) of this section, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of ''help wanted'' advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to the non- Federal entity's standard recruitment program. Where the non-Federal entity uses employment agencies, costs not in excess of standard commercial rates for such services are allowable. 2. Special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel that do not meet the test of reasonableness or do not conform with the established practices of the non-Federal entity, are unallowable. 3. Where relocation costs incurred incident to recruitment of a new employee have been funded in whole or in part as a direct cost to a Federal award, and the newly hired employee resigns for reasons within the employee's control within 12 months after hire, the non-Federal entity will be required to refund or credit the Federal share of such relocation costs to the Federal government. See also Relocation Costs of Employees. 4. Short-term, travel visa costs (as opposed to longer-term, immigration visas) are generally allowable expenses that may be proposed as a direct cost. Since short-term visas are issued for a specific period and purpose, they can be clearly identified as directly connected to work performed on a Federal award. For these costs to be directly charged to a Federal award, they must: a. Be critical and necessary for the conduct of the project; b. Be allowable under the applicable cost principles; c. Be consistent with the non-Federal entity's cost accounting practices and non-Federal entity policy; and d. Meet the definition of ''direct cost'' as described in the applicable cost principles. Project funds may not be used for a prospective trainee's travel costs to or from the recipient organization for the purpose of recruitment. However, other costs incurred in connection with recruitment under training programs, such as advertising, may be allocated to a grant-supported project according to the provisions of the applicable cost principles (also see Travel, Relocation Costs, and Visa Costs in this exhibit).

Items	Explanation of Allowable Costs
Registration Fees (for Symposiums and Seminars)	Allowable if necessary to accomplish project objectives.
Relocation Costs of Employees	Allowable—in other than change of recipient organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the recipient's benefit rather than the individual's and that payment is made according to established organizational policies consistently applied regardless of the source of funds. Relocation costs may include the cost of transporting the employee and their family, dependents, and household goods to the new location and certain expenses associated with the sale of the former home. If relocation costs have been incurred in connection with the recruitment of a new employee, whether as a direct cost or an F&A cost, and the employee resigns for reasons within their control within 12 months after hire, the recipient must credit the grant account for the full cost of the relocation charged to the grant. When there is a change in the recipient organization, the personal relocation expenses of the PD/PI and others moving from the original recipient to the new recipient are not allowable charges to NIH grants (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).
Rental or Lease of Facilities and Equipment	Allowable subject to the limitations below. Rental costs are allowable to the extent that the rates are reasonable at the time of the decision to lease in light of such factors as rental costs of comparable property, if any; market conditions in the area; the type, life expectancy, condition, and value of the property leased; and available alternatives. Because of the complexity involved in determining the allowable amount under certain types of leases, recipients are encouraged to consult the GMO before entering into leases that will result in direct charges to the grant project. In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. However, see Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for an exception to this general rule. Rental costs under leases that create a material equity in the leased property, as defined in 2 CFR Part 200 Subpart E, are allowable only up to the amount that would be allowed had the recipient purchased the property on the date the lease agreement was executed. This would include depreciation or use allowances, maintenance, taxes, and insurance, but would exclude unallowable costs. When a recipient transfers property to a third party through sale, lease, or otherwise, and then leases the property back from that third party, the lease costs that may be charged to NIH projects generally may not exceed the amount that would be allowed if the recipient continued to own the property. Rental costs under "less-than-arms-length" leases are allowable only up to the amount that would be allowed under 2 CFR Part 200, Subpart E and 45 CFR

Items	Explanation of Allowable Costs
	Part 75, Subpart E had title to the property been vested in the recipient. A less-than-arms-length lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest.
Research Patient Care	The costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers, participating in research programs are allowable. Incurrence of patient care costs if not previously approved by NIH and rebudgeting additional funds into, or rebudgeting approved amounts out of, the research patient care costs category may be considered a change in scope and require prior approval by the NIH awarding IC. Routine services include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made. Ancillary services are those special services for which charges customarily are made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology. See the Research Patient Care Costs chapter in IIB for NIH policy concerning reimbursement of these costs. The following otherwise allowable costs are not classified as research patient care costs: items of personal expense such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors. Such costs should be included in the "Other Expenses" category of the grant budget.
Reserve Funds	Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see Fringe Benefits/Insurance and Contingency Provisions in this exhibit).
Salaries and Wages / *IHEs - Part-time faculty*	Charges for work performed on Federal awards by faculty members having only part-time appointments will be determined at a rate not in excess of that regularly paid for part-time assignments.
Salaries and Wages / *IHEs - Periods outside the academic year*	1. Except as specified for teaching activity in paragraph (2) below, charges for work performed by faculty members on Federal awards during periods not included in the base salary period will be at a rate not in excess of the IBS. 2. Charges for teaching activities performed by faculty members on Federal awards during periods not included in IBS period will be based on the normal written policy of the IHE governing compensation to faculty members for teaching assignments during such periods.
Salaries and Wages / *IHEs - Sabbatical Leave Costs*	Sabbatical leave costs may be included in a fringe benefit rate or in the organization's F&A rate. Salary may be charged directly to a project for services

Items	Explanation of Allowable Costs
	rendered to the project by individuals while they are on sabbatical leave, provided the salary is proportional to the service rendered and is paid according to established organizational policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of that individual's regular salary from their organization.
Salaries and Wages / *Standards for Documentation of Personnel Expenses*	Salary and wage amounts charged to grant-supported projects for personal services must be based on an adequate payroll distribution system that documents such distribution in accordance with Federal Cost Principles and consistently applied institutional policy and practices. See 2 CFR Part 200.430(i) and 45 CFR Part 75.430.
Salaries and Wages	Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project. Compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reasonably reflect the percentage of time actually devoted to the NIH-funded project. Direct salary is exclusive of fringe benefits and F&A costs. This salary guidance does not apply to consultant payments or to contracts for routine goods and services but it does apply to consortium participants (see the Consortium Agreements chapter in IIB). Salaries of federal employees with permanent appointments are unallowable except in certain circumstances (see the Grants to Federal Institutions and Payments to Federal Employees Under Grants chapter in IIB).
Salaries and Wages / *Extra Service Pay (Overtime)*	Extra Service Pay normally represents overload compensation, subject to institutional compensation policies for services above and beyond IBS. Where extra service pay is a result of Intra-IHE consulting, it is subject to the reasonableness standards for Salaries and Wages above. It is allowable if all of the following conditions are met: 1. The non-Federal entity establishes consistent written policies which apply uniformly to all faculty members, not just those working on Federal awards. 2. The non-Federal entity establishes a consistent written definition of work covered by IBS which is specific enough to determine conclusively when work beyond that level has occurred. This may be described in appointment letters or other documentations. 3. The supplementation amount paid is commensurate with the IBS rate of pay and the amount of additional work performed. 4. The salaries, as supplemented, fall within the salary structure and pay ranges established by and documented in writing or otherwise applicable to the non-Federal entity.

Items	Explanation of Allowable Costs
	5. The total salaries charged to Federal awards including extra service pay are subject to the Standards of Documentation as described in Salaries and Wages/IHEs.
Salaries and Wages / *Institutions of higher education (IHEs)*	Certain conditions require special consideration and possible limitations in determining allowable personnel compensation costs under Federal awards. Allowable activities: Charges to Federal awards may include reasonable amounts for activities contributing and directly related to work under an agreement, such as delivering special lectures about specific aspects of the ongoing activity, writing reports and articles, developing and maintaining protocols (human, animals, etc.), managing substances/chemicals, managing and securing project-specific data, coordinating research subjects, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences.
Salaries and Wages / *Intra-IHE Consulting*	Intra-IHE consulting by faculty is assumed to be undertaken as an IHE obligation requiring no compensation in addition to IBS. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the faculty member is in addition to their regular responsibilities, any charges for such work representing additional compensation above IBS are allowable provided that such consulting arrangements are specifically provided for in the Federal award or approved in writing by the NIH awarding IC. Recipients, consortium participants, and contractors under grants that want to be able to charge employee consulting costs to grant-supported projects must establish written guidelines permitting such payments regardless of the source of funding and indicating the conditions under which the payment of consulting fees to employees is proper. Under no circumstances may an individual be paid as a consultant and an employee under the same NIH grant. Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be documented in writing, on a case-by-case basis, by the head of the organization (or their designee) incurring the costs – i.e., the recipient organization, consortium participant, or contractor. If the designee is personally involved in the project, the authorization may be given only by the head of the recipient organization, consortium participant, or contractor. This authorization must include a determination that the required conditions are present and that there is no apparent or actual conflict of interest.
Salaries and Wages / *Nonprofit Organizations*	For compensation to members of nonprofit organizations, trustees, directors, associates, officers, or the immediate families thereof, determination should be made that such compensation is reasonable for the actual personal services rendered rather than a distribution of earnings in excess of costs. This may include director's and executive committee member's fees, incentive awards, allowances for off-site pay, incentive pay, location allowances, hardship pay, and cost-of-living differentials.
Salaries and Wages / *Professional Activities outside of the Non-*	Unless an arrangement is specifically authorized by an NIH awarding IC, a non-Federal entity must follow its written non-Federal entity-wide policies and

Items	Explanation of Allowable Costs
Federal Entity	practices concerning the permissible extent of professional services that can be provided outside the non-Federal entity for non-organizational compensation. Where such non-Federal entity-wide written policies do not exist or do not adequately define the permissible extent of consulting or other non-organizational activities undertaken for extra outside pay, the Federal government may require that the effort of professional staff working on Federal awards be allocated between: 1. Non-Federal entity activities, and 2. Non-organizational professional activities. If the NIH awarding IC considers the extent of non-organizational professional effort excessive or inconsistent with the conflicts-of-interest terms and conditions of the Federal award, appropriate arrangements governing compensation will be negotiated on a case-by-case basis.
Salaries and Wages / *Special Considerations*	Special considerations in determining allowability of compensation will be given to any change in a non-Federal entity's compensation policy resulting in a substantial increase in its employees' level of compensation (particularly when the change was concurrent with an increase in the ratio of Federal awards to other activities) or any change in the treatment of allowability of specific types of compensation due to changes in Federal policy.
Salaries and Wages / *Unallowable Costs*	1. Costs which are unallowable under other sections of these principles must not be allowable under this section solely on the basis that they constitute personnel compensation. 2. The allowable compensation for certain employees is subject to a ceiling in accordance with statute. For the amount of the ceiling for cost reimbursement contracts, the covered compensation subject to the ceiling, the covered employees, and other relevant provisions, see 10 U.S.C. 2324(e)(1)(P), and 41 U.S.C. 1127 and 4304(a)(16). For other types of Federal awards, other statutory ceilings may apply.
Salaries and Wages /*Incentive Compensation*	Incentive compensation to employees based on cost reduction, or efficient performance, suggestion awards, safety awards, etc., is allowable to the extent that the overall compensation is determined to be reasonable and such costs are paid or accrued pursuant to an agreement entered into in good faith between the non-Federal entity and the employees before the services were rendered, or pursuant to an established plan followed by the non-Federal entity so consistently as to imply, in effect, an agreement to make such payment.
Salaries and Wages /*Overtime Premiums*	Premiums for overtime generally are allowable; however, such payments are not allowable for faculty members at institutions of higher education. If overtime premiums are allowable, the categories or classifications of employees eligible to receive overtime premiums should be determined according to the formally established policies of the organization consistently applied regardless of the source of funds.
Salaries and Wages /*Payments for Dual*	For investigators receiving compensation from the institution (recipient/contractor) and separately organized clinical practice plans,

Items	Explanation of Allowable Costs
Appointments	compensation from such sources may be included in the institutional base salary (IBS) budgeted and charged to NIH sponsored agreements if all of the following criteria are met: • Clinical practice compensation must be set by the institution. * • Clinical practice activity must be shown on the institution's payroll or salary appointment forms and records approved by the institution. • Clinical practice compensation must be paid through or at the direction of the institution. • Clinical practice activity must be included and accounted for in the institution's effort reporting and/or payroll distribution system. • The institution must assure that all financial reports and supporting documents associated with the combined IBS and resulting charges to NIH grants are retained and made available to Federal officials or their duly authorized representatives consistent with the requirements of 2 CFR Part 200.430 and 45 CFR Part 75.430. * "Set by the institution" means the recipient/contractor institution must be in a position to document and certify that the specified amount of clinical practice compensation is being paid in essentially the same manner as other specified amounts of the committed IBS (compensation) of the investigator. Further, this requires that the IBS not vary based on the specific clinical services provided by investigator within the periods for which total IBS is certified by the recipient institution.
Salaries and Wages /*Support from Multiple Grants*	See Cost Considerations—Allocation of Costs and Closely Related Work.
Selling and Marketing Costs	Costs of selling and marketing any products or services of the non-Federal entity (unless allowed under 2 CFR Part 200.421 and 45 CFR Part 75.421) are generally not allowable, except as direct costs, with prior approval by the NIH awarding IC when necessary for the performance of the Federal award.
Service Charge	Allowable. The costs to a user of organizational services and central facilities owned by the recipient organization, such as central laboratory, technology infrastructure fees, computer services and next generation computing/communication costs, are allowable provided that they are not covered by F&A costs. They must be based on organizational fee schedules consistently applied regardless of the source of funds.
Specialized Service Facilities	1. The costs of services provided by highly complex or specialized facilities operated by the non-Federal entity, such as computing facilities, wind tunnels, and reactors are allowable, provided the charges for the services meet the conditions of either paragraphs (b) or (c) of this section, and, in addition, take into account any items of income or Federal financing that qualify as applicable credits under 2 CFR Part and 45 CFR Part 75.406.

Items	Explanation of Allowable Costs
	2. The costs of such services, when material, must be charged directly to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology that: a. Does not discriminate between activities under Federal awards and other activities of the non-Federal entity, including usage by the non- Federal entity for internal purposes, and b. Is designed to recover only the aggregate costs of the services. The costs of each service must consist normally of both its direct costs and its allocable share of all indirect (F&A) costs. Rates must be adjusted at least biennially, and must take into consideration over/under applied costs of the previous period(s). c. Where the costs incurred for a service are not material, they may be allocated as indirect (F&A) costs. d. Under some extraordinary circumstances, where it is in the best interest of the Federal government and the non-Federal entity to establish alternative costing arrangements, such arrangements may be worked out with the Federal cognizant agency for indirect costs.
Stipends	Allowable as cost-of-living allowances for trainees and fellows only under Kirschstein-NRSA individual fellowships and institutional research training grants. These payments are made according to a preestablished schedule based on the individual's experience and level of training. A stipend is not a fee-for-service payment and is not subject to the cost accounting requirements of the cost principles. Additional information, including NIH policy on stipend supplementation, is included in Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Supplementation of Stipends, Compensation, and Other Income—Stipend Supplementation and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Stipend Supplementation, Compensation, and Other Income—Stipend Supplementation in IIB. Stipends are not allowable under research grants even when they appear to benefit the research project. See Fringe Benefits / IHE Tuition/Tuition Remission in this exhibit.
Subject Costs	See Research Patient Care and Donor Costs in this exhibit.
Taxes	For nonprofit organizations and IHEs: 1. In general, taxes which the non-Federal entity is required to pay and which are paid or accrued in accordance with GAAP, and payments made to local governments in lieu of taxes which are commensurate with the local government services received are allowable, except for: a. Taxes from which exemptions are available to the non-Federal entity directly or which are available to the non-Federal entity based on an exemption afforded the Federal government and, in the latter case, when the NIH awarding IC makes available the necessary exemption certificates,

Items	Explanation of Allowable Costs
	b. Special assessments on land which represent capital improvements, and c. Federal income taxes. 2. Any refund of taxes, and any payment to the non-Federal entity of interest thereon, which were allowed as Federal award costs, will be credited either as a cost reduction or cash refund, as appropriate, to the Federal government. However, any interest actually paid or credited to an non-Federal entity incident to a refund of tax, interest, and penalty will be paid or credited to the Federal government only to the extent that such interest accrued over the period during which the non-Federal entity has been reimbursed by the Federal government for the taxes, interest, and penalties.
Termination or Suspension Costs	Unallowable except as follows. If a grant is terminated or suspended, the recipient may not incur new obligations after the effective date of the termination or suspension and must cancel as many outstanding obligations as possible (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support). NIH will allow full credit to the recipient for the Federal share of otherwise allowable costs if the obligations were properly incurred by the recipient before suspension or termination—and not in anticipation of it—and, in the case of termination, are not cancelable. The GMO may authorize other costs in, or subsequent to, the notice of termination or suspension.
Trailers and Modular Units	Allowable only if considered equipment as provided below. A “trailer” is defined as a portable vehicle built on a chassis that is designed to be hauled from one site to another by a separate means of propulsion and that serves, wherever parked, as a dwelling or place of business. A “modular unit” is a prefabricated portable unit designed to be moved to a site and assembled on a foundation to serve as a dwelling or a place of business. The determination of whether costs to acquire trailers or modular units are allowable charges to NIH grant-supported projects depends on whether such units are classified as real property or equipment. The classification will depend on whether the recipient’s intended use of the property is permanent or temporary. A trailer or modular unit is considered real property when the unit and its installation are designed or planned to be installed permanently at a given location so as to seem fixed to the land as a permanent structure or appurtenance thereto. Units classified as real property may not be charged to an NIH grant-supported project unless authorizing legislation permits construction or acquisition of real property and the specific purchase is approved by the NIH awarding IC. A trailer or modular unit is considered equipment when the unit and its installation are designed or planned to be used at any given location for a limited time only. Units classified as equipment may be charged to NIH grant-supported projects only if the terms and conditions of the award do not prohibit the purchase of equipment and NIH prior approval is obtained, as appropriate. A trailer or modular unit properly classified as real property or as equipment at

Items	Explanation of Allowable Costs
	the time of acquisition retains that classification for the life of the item, thereby determining the appropriate accountability requirements under 2 CFR Part 200.439 or 200.465 and 45 CFR Part 75.439, as applicable.
Trainee Costs	Allowable only under predoctoral and postdoctoral training grants. (See Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs in IIB for detailed information).
Transportation Costs	Costs incurred for freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the materials received cannot readily be made, inbound transportation cost may be charged to the appropriate indirect (F&A) cost accounts if the non-Federal entity follows a consistent, equitable procedure in this respect. Outbound freight, if reimbursable under the terms and conditions of the Federal award, should be treated as a direct cost.
Travel	Allowable as a direct cost where such travel will provide direct benefit to the project.
Travel/*Employees*	Consistent with the organization's established travel policy, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile. Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the United States and its possessions and territories and also travel between the United States and Canada and within Canada. Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country. In all cases, travel costs are limited to those allowed by formally established organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. Commercial recipients' allowable travel costs may not exceed those established by the FTR, issued by GSA, including the maximum per diem and subsistence rates prescribed in those regulations. This information is available at http://www.gsa.gov. If a recipient organization has no established travel policy, those regulations will be used to determine the amount that may be charged for travel costs. Recipients are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets if travel schedules can be planned in advance (such as for national meetings and other scheduled events). Recipients must comply with the requirements of the Fly America Act (49 U.S.C. 40118) which generally provides that foreign air travel funded by Federal funds may only be conducted on U.S. flag air carriers and under applicable Open Skies Agreements. For additional information regarding the Fly America Act and its

Items	Explanation of Allowable Costs
	exceptions, see Public Policy Requirements and Objectives—Fly America Act. Applicants and recipients should consult application instructions to determine how to budget for travel costs under specific mechanisms and for certain types of travelers, because they are not all required to be budgeted as travel (e.g., research subjects).
Travel/*Research Patients*	If research patient care is an approved activity of the grant-supported project, the costs of transporting individuals participating in the research protocol to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose also may be allowable. (See also Research Patient Care in this exhibit).
Value Added Tax (VAT)	Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. Foreign tax refunds or applicable credits under Federal awards refer to receipts, or reduction of expenditures, which operate to offset or reduce expense items that are allocable to Federal awards as direct or indirect costs. To the extent that such credits accrued or received by the non-Federal entity relate to allowable cost, these costs must be credited to the NIH awarding IC either as costs or cash refunds. If the costs are credited back to the Federal award, the non-Federal entity may reduce the Federal share of costs by the amount of the foreign tax reimbursement, or where Federal award has not expired, use the foreign government tax refund for approved activities under the Federal award with prior approval of the NIH awarding IC. For many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.
Visa Costs (including short-term travel visa costs)	Generally, allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual. Visa costs may also be allowable when identified in specific FOAs or when within the scope of an approved research project. Visa renewal costs for employees is not a recruiting cost and would not be an allowable charge to a grant. Expedited processing fees are generally unallowable unless and until they become part of standard processing fees. Fraud prevention and detection fees are allowable if they are required fees. Department of Homeland Security SEVIS Form I-901 is a required fee and is allowable. See also Recruiting Costs in this exhibit.

8 ADMINISTRATIVE REQUIREMENTS

8.1 CHANGES IN PROJECT AND BUDGET

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities. The recipient-initiated changes that may be made under the recipient's authority and the changes that require NIH approval are outlined below and, with respect to particular types of awards, activities, or recipients, in Subpart IIB. In addition, individual awards may restrict recipients' authorities to make budget and project changes without NIH prior approval. If NIH approval is required, it must be requested of, and obtained in writing from, the awarding IC GMO in advance of the change or obligation of funds as specified later in this chapter under Requests for Prior Approval.

Recipients shall immediately notify the Federal awarding agency of developments that have a significant impact on the award-supported activities. This includes significant changes to Other Support (e.g. new appointments or affiliations) that occur during the award. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

Changes in project or budget resulting from NIH-initiated actions are discussed in other sections of this chapter.

8.1.1 NIH Standard Terms of Award

Federal administrative requirements allow agencies to waive certain cost-related and administrative prior approvals; these are known as expanded authorities. In 2001, NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances. Certain award instruments, grant programs, and types of recipients are routinely excluded from the authority to automatically carry over unobligated balances. This includes centers (P50, P60, P30, and others); cooperative agreements (U); Kirschstein-NRSA institutional research training grants (T); non-Fast Track Phase 1 SBIR and STTR awards (R43 and R41); clinical trials (regardless of activity code); and awards to individuals.

One or more of these authorities may be overridden by a specific term or condition of the award. Recipients must review the NoA to determine if a particular authority is withheld for a specific grant.

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. NIH may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

Several authorities have specific deadlines for submission of reports or for timely notification to the NIH awarding IC. Recipients should be aware that any consistent pattern of failure to adhere to those deadlines for reporting or notification will be grounds for excluding that recipient from a specific authority.

Exhibit 6. Summary of NIH Standard Terms of Award

Recipient Authorities as NIH Standard Terms of Award	Exceptions
Carryover of unobligated balances from one budget period to any subsequent period	Centers (P50, P60, P30 and others), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NoA indicates otherwise.
Cost-related prior approval changes, including research patient care costs and equipment	The cost would result in a change of scope.
Extension of final budget period of a project period without additional NIH funds (no-cost extension)	The recipient has already exercised its one-time authority to extend the award for up to 12 months; the NIH awarding IC has previously extended the project period; and/or a project is multi-year for 5 years (i.e., the entire 5-year project period is funded by a single award).
Transfer of performance of substantive programmatic work to a third party (by consortium agreement)	The transfer would be to a foreign component or it would result in a change in scope.
Direct charge the salaries of administrative and clerical staff if conditions in 2 CFR Part 200.413 and 45 CFR Part 75.413 are met and the charges also meet the criteria for allowable costs described in 2 CFR Part 200.403 and 45 CFR Part 75.403.	
Direct charge payments of Incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) 2 CFR Part 200.430 and 45 CFR Part 75.430. Such activities must be specifically provided for in the Federal award budget.	
Include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member's base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member's regular departmental load.	

8.1.1.1 Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period

Recipients should be aware that there is a difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the recipient and are considered to be obligations and, therefore, should not be reported as unobligated balances.

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority, or if prior approval is required by the NIH awarding IC. Note the authority to automatically carry over unobligated balances includes the authority to carryover from one competitive segment to another.

Automatic carryover of unobligated balances applies to all awards except centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials (regardless of activity code), and awards to individuals. For these grants, carryover of unobligated balances requires NIH awarding IC prior approval unless otherwise noted in the NoA. Other awards may be excluded from this authority through a specific term or condition in the NoA.

For awards under SNAP (see Administrative Requirements—Monitoring—Reporting—Streamlined Non-Competing Award Process for applicability), funds are automatically carried over to the subsequent budget period. However, the recipient will be required to indicate, as part of the grant's progress report, whether any estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. The total approved budget amount includes current year and any carryover from prior years of the project period. If the unobligated balance is greater than 25 percent of the total approved budget, the recipient must provide an explanation and indicate plans for expenditure of those funds within the current budget year.

For awards that require an annual FFR, the amount to be carried over must be specified under item 12, "Remarks."

For both SNAP and non-SNAP, when a recipient reports a balance of unobligated funds in excess of 25 percent of the total amount awarded for the budget period, plus any approved carryover of funds from a prior year(s), the GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the recipient, including a revised budget, as part of the review.

If the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may restrict the recipient's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset NIH funding for a subsequent budget period, or use a combination of these actions. The GMO also may indicate whether the balance may be carried forward to a budget period other than the succeeding one. The GMO's decision about the disposition of the reported unobligated balance will be reflected in the terms and conditions of the NoA.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30th, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit the availability of funds for carryover.

8.1.1.2 Cost-Related Prior Approvals

NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope.

8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds

The recipient may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original completion date shown in the NoA if:

- no term of award specifically prohibits the extension,
- no additional funds are required to be obligated by the NIH awarding IC, and
- the project's originally approved scope will not change.

Such an action affirms that additional work remains to be completed on the project and that resources are available to continue to support the project, or that additional time is needed to provide for an orderly closeout. The fact that funds remain at the completion date of the grant is not, in itself, sufficient justification for an extension without additional funds.

With the exception of grant programs that have an effort requirement, or where terms and conditions prohibit such reductions, NIH will not require prior approval for the reduction in effort for Senior/Key personnel named in the NOA. The recipient is reminded that active awards must have a measurable level of effort.

Recipients must use the eRA Commons No-Cost Extension feature to electronically notify NIH that they are exercising their one-time authority to extend without funds the completion date of an award. This extension feature becomes available to the recipient 90 days before the project period end date. Extensions may be up to 12 months beyond the final budget period end date. In the eRA Commons, this notification can be made up to the last day of the current project end date. An e-mail notification is automatically sent to the GMO. No further action by the recipient is required.

Notifications may not be submitted via e-mail or fax. If a no-cost extension notification is submitted late, the eRA Commons No-Cost Extension feature cannot be used. Instead, the extension notification becomes a request and that requires the approval of the IC GMO. Recipients who miss the window (or opportunity) to extend the grant in eRA Commons must submit a written prior approval request to the NIH awarding IC for consideration. (See Administrative Requirements—Prior Approval Requirements for extension requiring additional funds.)

In extending the final budget period of the project period through this process, the recipient agrees to update all required certifications and assurances, including but not limited to those pertaining to human subjects and vertebrate animals, in accordance with applicable regulations and policies. Recipients are reminded that all terms and conditions of the award apply during the extension period.

Recipients may not extend project periods that were previously extended by the NIH awarding IC. Any additional project period extension requires NIH prior approval. (See Administrative Requirements—Prior Approval Requirements for extensions requiring additional funds.)

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit or eliminate this authority to extend the final budget period when an entire project period is funded by a single award (e.g., multiyear funded awards).

The provisions in this subsection do not apply to fellowship awards.

8.1.1.4 Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement

Prior approval by the NIH awarding IC is not required to transfer the performance of already peer reviewed programmatic work unless the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

8.1.1.5 Direct Charging Salaries of Administrative and Clerical Staff

The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:

1. Administrative or clerical services are integral to a project or activity;
2. Individuals involved can be specifically identified with the project or activity;
3. Such costs are explicitly included in the budget; and
4. The costs are not also recovered as indirect costs.

Such charges must also meet the criteria for allowable costs described in 2 CFR Part 200.403 and 45 CFR Part 75.403.

NIH prior approval is not required to rebudget funds for this direct cost item post-award. Prior approval is only required when additional funds are being requested for such a position.

8.1.1.6 Supplemental Compensation under Written Institutional Policy for IHEs

IHEs may direct charge payments of incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) and not include them in the records described in 2 CFR Part 200.430 and 45 CFR Part 75.430. Such activities must be specifically provided for in the Federal award budget.

8.1.1.7 Intra-IHE Faculty Consulting that Exceed a Faculty Member's Base Salary, Under Certain Conditions.

IHEs may include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member’s base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member’s regular departmental load.

8.1.2 Prior Approval Requirements

This section describes the activities and/or expenditures that require NIH prior approval. NIH prior approval requirements are summarized in Exhibit 7, which is provided for guidance only. For the prior approval requirements specified in the exhibit, approval is required whether or not the change has a budgetary impact. The circumstances under which prior approval is required also are summarized in the exhibit.

Recipients also should consult Subpart IIB for prior approval requirements that apply to specific mechanisms, types of grants, and types of recipients.

Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to the GMO.

Exhibit 7. Summary of Actions Requiring NIH Prior Approval

NIH prior approval is required for	Under the following circumstances
Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension (8.1.2.1)	All instances.
A&R (8.1.2.2)	Rebudgeting into A&R costs that would exceed 25 percent of the total approved budget for a budget period. If rebudgeting would not meet this threshold but would result in a change in scope. Addition of a Major single A&R project.
Capital expenditures (construction, land, or building acquisition) (8.1.2.3)	All instances. Also, any proposals to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds.
Carryover of unobligated balances (8.1.2.4)	If the NoA indicates that the recipient does not have the authority to automatically carry over unobligated balances.
Change in scope (8.1.2.5)	All instances.
Change in status of the PD/PI or senior/key personnel named in the NoA (8.1.2.6)	A significant change in the status including but not limited to withdrawal from the project; absence for any continuous period of 3 months or more; reduction of the level of effort devoted to project by 25 percent or more from what was approved in the initial competing year award.
Change of recipient organization (8.1.2.7)	All instances.
Change of recipient organization status (8.1.2.8)	All instances.
Deviation from award terms and conditions (8.1.2.9)	All instances. Includes undertaking any activities disapproved or restricted as a condition of the award.
Foreign component added to a grant to a domestic or foreign organization (8.1.2.10)	All instances.
Make subawards based on fixed amounts (8.1.2.11)	All instances
Need for additional NIH funding (8.1.2.12 and 8.1.2.13)	All instances, including extension of a final budget period of a project period with additional funds.
Pre-award costs (8.1.2.14)	More than 90 days before effective date of the initial budget period of a new or competing continuation award; always at the recipient's own risk.

NIH prior approval is required for	Under the following circumstances
Rebudgeting funds from trainee costs (8.1.2.15)	All instances.
Rebudgeting of funds between construction and non-construction work (8.1.2.16)	All instances.
Retention of research grant funds when CDA awarded (8.1.2.17)	All instances.

8.1.2.1 Additional No-cost Extension or Extension Greater Than 12 Months or Late Notification of Initial No-Cost Extension

The NIH Standard Terms of Award provide the recipient the authority to extend the final budget period of a previously approved project period one time for a period of up to 12 months beyond the original completion date down in the NoA. Any additional project period extension beyond the initial extension of up to 12 months requires NIH prior approval. The request should include a description of the project activities that require support during the extension and a statement about the funds available to support the extension. Further any late notification of the initial no-cost extension provided by the NIH Standard Terms of Award also requires prior approval.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period.

8.1.2.2 Alterations and Renovations

NIH prior approval is required if a recipient wishes to rebudget more than 25 percent of the total approved budget for a budget period into A&R costs. NIH prior approval also is required for lesser rebudgeting into A &R costs if the rebudgeting would result in a change in scope. If rebudgeting results in the addition of a Major A&R project , NIH will consider the rebudgeting to be a change in scope. (See the Construction Grants chapter in IIB for documentation requirements for Major A&R projects).

8.1.2.3 Capital Expenditures

Capital expenditures for land or buildings require NIH prior approval. In addition, real property acquired with NIH grant funds may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient without the written prior approval of the NIH awarding IC or its successor organization.

8.1.2.4 Carryover of Unobligated Balances

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority or if prior approval is

required by the NIH awarding IC. When NIH prior approval is required, the AOR should submit a request to the GMO that includes at a minimum the following information:

- A detailed budget by direct cost category with the F&A cost information (base and rate) for the proposed use of the carryover funds. If personnel costs are requested, include a detailed breakdown of personnel costs, including base salary, salary requested and effort to be spent on the project during the extension. In general, carryover action requiring prior approval will be approved using the F&A rate that was in effect at the time the initial funds were awarded for the year to which the funds are being carried over. For example, if the carryover is approved from year -01 to year -03, the F&A rate used to calculate the revised -03 year award will be the rate used to initially calculate year -03. However, actual expenditures will still be based on the rate applicable when the cost is incurred.
- A scientific justification for the use of funds.
- The reason for the unobligated balance.

8.1.2.5 Change in Scope

In general, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the recipient must obtain prior approval from the NIH awarding IC for a change in scope. A change in scope is a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project. The recipient must make the initial determination of the significance of a change and should consult with the GMO as necessary.

Potential indicators of a change in scope include, but are not limited to, the following:

- Change in the specific aims approved at the time of award.
- Substitution of one animal model for another.
- Change from the approved use of live vertebrate animals.

- Change from the approved involvement of human subjects that would result in an increased risk. This includes:
    - An addition or change that would result in changing the overall human subjects or clinical trial designation of the award;
        - From non-human subjects research to human subjects research (exempt or non-exempt);
        - From exempt to non-exempt human subjects research; or
        - From "No Clinical Trial" to "Includes a Clinical Trial." Requests for this change must be submitted to a clinical trial FOA as a competitive revision. See NIH definition of clinical trial and 2.3.5 - Types of Funding Opportunity Announcements.
    - The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR Part 46 subparts B, C or D (pregnant women, human fetuses, and neonates; prisoners; or children).
    - Any change to the study protocol that would increase the risk level for subjects including physical, psychological, financial, legal or other risks. This could include the addition of a new study population that would be at higher risk from existing research procedures, the addition of new study procedures that are greater than minimal risk, any modification of existing study procedures that would increase overall risk, or the addition of a new clinical study or a new clinical trial intervention arm not originally proposed that is greater than minimal risk.
    - New information indicating a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.
- Shift of the research emphasis from one disease area to another.
- A clinical hold by FDA under a study involving an IND or an IDE.
- Application of a new technology, e.g., changing assays from those approved to a different type of assay.
- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. If the third party is a foreign component, NIH prior approval is always required.
- Change in other senior/key personnel not specifically named in the NoA (see Change in Status, Including Absence, of PD/PI and Other Senior/Key Personnel Named in the NoA below for requirements for NIH approval of alternate arrangements for or replacement of named senior/key personnel).
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded. For example, if the award budget for total costs is $200,000, any rebudgeting that would result in an increase or decrease of more than $50,000 in a budget category is considered significant rebudgeting. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements. Significant rebudgeting does not apply to modular grants.

- Incurrence of research patient care costs if costs in that category were not previously approved by NIH or if a recipient desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category.
- Purchase of a unit of equipment exceeding $25,000.

8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA

The recipient is required to submit a prior approval request to the GMO if:

- There is a significant change in the status of the PD/PI or other Senior/Key Personnel specifically named in the NoA including but not limited to withdrawing from the project entirely, being absent from the project during any continuous period of 3 months or more, or reducing time devoted to the project by 25 percent or more from the level that was approved at the time of initial competing year award (for example, a proposed change from 40 percent effort to 30 percent or less effort or in calendar months a change from 4.8 to 3.6 calendar months). Reductions are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more. Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level. Selecting **Yes** in the RPPR constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request.
- There is a change from a multiple PD/PI model to a single PD/PI model.
- There is a change from a single PD/PI model to a multiple PD/PI model.
- There is a change in the number or makeup of the PD/PIs on a multiple PD/PI award.

NIH must approve any alternate arrangement proposed by the recipient, including any replacement of the PD/PI or senior/key personnel named in the NoA, and the addition of any new PD/PIs.

The request for prior approval of any additional or substitute PD/PIs or Senior/Key Personnel named in the NoA, or change from a multiple PD/PI model to a single PD/PI model, must be submitted promptly, and must be accompanied by a strong scientific justification related to the scientific project, including any proposed changes in scope, the biographical sketch of any new individuals proposed and other sources of support, and any budget changes resulting from the proposed change. A new or revised Leadership Plan is required if the request is to change from a single PD/PI model to a multiple PD/PI model, or to change the number or makeup of the PD/PIs on a multiple PD/PI award. The Commons ID must be provided for any new PD/PIs.

In addition, because NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research, the request for approval should include mention as to whether change(s) in PD/PI or Senior/Key Personnel is related to concerns about safety and/or work environments (bullying, retaliation, or hostile working conditions). NIH recipient institutions are required to notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions. Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must be submitted to NIH through a dedicated web form. All required notifications must include, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action(s) taken, and any anticipated impact on the NIH-funded award(s). If it is determined that the concerns shared with NIH will impact the PD/PI or senior key personnel's ability to continue as

the scientific lead of the project, NIH will require prior approval for a replacement PD/PI or senior key official.

NIH will, in turn, be better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight.

If the arrangements proposed by the recipient, including the qualifications of any proposed replacement, are not acceptable to the NIH awarding IC, the grant may be suspended or terminated. If the recipient wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the GMO, in writing, of its wish to terminate, and NIH will forward closeout instructions.

The requirement to obtain NIH prior approval for a change in status pertains only to those personnel NIH designates in the NoA regardless of whether the applicant organization designates others as senior/key personnel for its own purposes.

8.1.2.7 Change of Recipient Organization

NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment). A change of recipient organization may be accomplished under most NIH grants if any of the following conditions are met:

- The original recipient has agreed to relinquish responsibility for an active project before the completion date of the approved project period. This includes any proposed change of recipient as a result of a PD/PI on a research project transferring from one organization to another organization. The project under the same PD/PI may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable F&A costs) for the remaining period.
- A non-competing continuation award that is within an approved project period has been withheld because of the recipient's actions (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support).

A request for change of recipient organization should include mention as to whether the change in recipient institution is related to concerns about safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions) involving the PD/PI. NIH recipient institutions are required to notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions. Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must be submitted to NIH through a dedicated web form. All required notifications must include, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action (s) taken, and any anticipated impact on the NIH-funded award(s). If it is determined that the concerns shared with NIH will impact the PD/PI or senior key personnel's ability to continue as the scientific lead of the project, NIH will require prior approval for a replacement PD/PI or senior key official.

NIH will, in turn, be better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight.

NIH expects both the relinquishing and applicant organizations to disclose whether a Change of Recipient Organization is occurring within the context of an ongoing or recent investigation of misconduct of any kind, including but not limited to professional misconduct or research misconduct.

A change of recipient that involves the transfer of a grant to or between foreign organizations or international organizations also must be approved by the IC's Advisory Council or Board.

A grant to an individual may not be transferred.

A successor-in-interest or a name change is not considered a change of recipient (see Change in Recipient Organizational Status below).

A change of recipient organization may involve the transfer of equipment purchased with grant funds. The transfer may be accomplished as part of the original recipient's relinquishment of the grant; otherwise, NIH reserves the right to transfer title to equipment to the new organization as indicated in Administrative Requirements—Management Systems and Procedures—Property Management System Standards.

A change of recipient request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any proposed changes in the scope of the project. NIH will also consider the length of time, the percentage of funds, and the amount of work remaining in the project period. A change may be made without peer review, provided the PD/PI plans no significant change in research objectives and the facilities and resources at the new organization will allow for successful performance of the project. If these conditions or other programmatic or administrative requirements are not met, the NIH awarding IC may require peer review or may disapprove the request and, if appropriate, terminate the award.

A change of recipient organization request must be made before the anticipated start date at the new organization and preferably several months in advance. Failure to provide timely notification may result in disapproval of the request or significant delays in processing. Recipients are encouraged to discuss any potential issues with the awarding IC(s) prior to submitting a change of recipient organization request. If requesting a transfer in the middle of a budget period or at the end of the Federal fiscal year, recipients should contact the awarding IC for IC-specific guidance on the timing and preparation of the change of institution application.

A request for a change of recipient organization must be submitted to the GMO. The original institution must include an Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant (PHS 3734) (relinquishing statement). The relinquishing statement may be submitted in paper or electronically via the eRA Commons. Final FFR Expenditure Data and a Final Invention Statement are due to NIH from the relinquishing organization no later than 120 days after the end of NIH support of the project. Final FFR Expenditure Data should not be submitted until the original institution has received a revised NoA for the relinquished grant.

The proposed new recipient institution must provide the GMO with a change of institution application which may be submitted using the PHS 398 or PHS 416-1 paper application forms, or electronically via Grants.gov using the Parent Funding Opportunity Announcement. If the original award was the result of a modular application and the recipient will submit a paper change of institution application, the modular procedures apply to the request for change of recipient. If the original award was the result of a modular application and the recipient will submit an electronic change of institution application, the recipient may submit a detailed budget or streamlined-detailed budget (as described in the FOA).

The paper application from the proposed new recipient institution should include, at a minimum, the following:

- PHS 398 Face page
- Budget pages (current and future years). (Under awards resulting from modular applications, the application should include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.) Budgets should not exceed the direct costs (plus applicable F&A costs) previously recommended for any budget period. For transfers in the middle of a budget period, the budget for the initial year may be based on the total costs relinquished only if the recipient has been instructed to do so by the awarding IC. For these applications, recipients will also need to include the Other Project Information and the Senior/Key Personnel components.
- Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel.
- If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- Updated "other support" page(s), if necessary.
- Resources page, including probable effect of the move on the project.
- Checklist page
- Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
- Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment).

The electronic application from the proposed recipient institution should include, at a minimum, the following:

- SF 424 (R&R) Cover Component
- SF 424 (R&R) Project Performance Site Location(s)
- SF 424 (R&R) Other Project Information:
    - Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
    - Facilities and Other Resources, including probable effect of the move on the project.
    - Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of the list in the transfer application from the new organization indicates its acceptance of title to that equipment).
- SF 424 (R&R) Senior/Key Person Profile:
    - Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel, and updated "other support" page(s) as necessary.

- Budget pages applicable for activity code (current and future years). If the budget for the original award was submitted in a modular format, use the R&R Detailed Budget form for all electronic applications. Recipients may either complete all of the fields in the R&R Detailed Budget as appropriate or complete only the costs for the PD/PI (Section A), and include the remainder of the direct costs under Section F (Other Direct Costs) Item 8, and Section H (Indirect Costs). (For awards resulting from modular applications, include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.) Budgets should not exceed the direct costs previously recommended for direct costs (plus applicable F&A costs) for any budget period. For transfers during the course of a budget period, the budget for the initial year may be based on the total costs relinquished only if the recipient has been instructed to do so by the awarding IC.
- PHS 398 Research Plan
    - If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- PHS 398 Cover Page Supplement
- PHS 398 Checklist

And, as applicable:

- PHS 398 Career Development Supplemental Form
- PHS 398 Fellowship Supplemental Form
- SBIR/STTR Information

NIH may request additional information necessary to accomplish its review of the request. Acceptance of a relinquishing statement by NIH does not guarantee approval of a transfer application for the continued funding of a project.

NIH will accomplish a change of recipient organization by issuing a revised NoA to the original recipient reflecting the revised budget/project period end dates, deletion of any future-year support, and deobligation of remaining funds, if applicable. (A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement or the available balance in PMS, whichever is less.)

Concurrently, the new recipient will receive the NoA reflecting the direct cost balance reported on the relinquishing statement plus applicable F&A costs, if funds are available. If the change of recipient organization occurs on the anniversary date of the project, the NoA to the new recipient will reflect the previously committed direct cost level plus applicable F&A costs if funds are available. If the change of recipient organization occurs during the course of the budget period, the policy of the awarding IC will determine if the NoA to the new recipient will reflect the direct cost relinquished by the former recipient plus applicable F&A costs or the total costs relinquished by the former recipient. This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward.

A recipient may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs before the beginning date of a transfer award. The recipient may do so only if those costs are necessary to conduct the project and would not require prior approval if incurred under an awarded grant. For the purposes of pre-award costs, transfers are treated like non-competing continuation awards. Therefore, the pre-award costs incurred are not limited to 90 days prior to the beginning date of the initial budget period of that transferred award to the new recipient organization.

8.1.2.8 Change in Recipient Organizational Status

Recipients must give NIH advance notice of the following types of change in organizational status (not a change of recipient organization as described above):

- ***Merger.*** Legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change normally will apply.
- ***Successor-in-Interest (SII).*** Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
- ***Name Change.*** Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.

Advance notification is required to ensure that the recipient remains able to meet its legal and administrative obligations to NIH, and payments are not interrupted.

Recipients are encouraged to contact the GMO of the lead NIH awarding IC to explain the nature of the change in organizational status and receive guidance on whether it will be treated as a name change or SII. The lead awarding IC ordinarily will be the IC with which the organization has the most NIH grants. NIH reserves the right to review the material provided, seek clarification or additional information, and make an independent determination.

A recipient's formal request for a change in organizational status should be submitted to NIH as soon as possible so that NIH can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For a SII, a letter signed by the AORs of the current recipient (transferor) and the successor-in-interest (transferee) must be sent to the lead NIH awarding IC, following consultation with the GMO of that awarding IC. The letter must include the following:

- Stipulate that the transfer will be properly affected in accordance with applicable law.
- Indicate that the transferor relinquishes all rights and interests in all of the affected grants.
- Request that the awarding IC(s) modify its (their) records to reflect the transferee as the recipient of record.
- State the effective date of the transfer.
- Provide the transferee's EIN. If EIN is new, include completed Form W-9.
- Include verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance).

- Include a list of all affected NIH grants (active and pending) with the following information for each:
    - Complete grant number (e.g., 5 R01 GM 12345-04).
    - Name(s) of PD/PI(s).
    - Current budget period and project period.
    - The total direct costs (as originally recommended) plus applicable F&A costs for each remaining budget period. If the SII will occur during a budget period rather than on the anniversary date, the transferor also must provide estimated levels of current-year direct and F&A costs remaining as of the SII effective date. The estimate may be reported on the PHS 3734 (Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant), which may be submitted on paper or electronically through the eRA Commons, or may be itemized by grant number as an attachment to the letter. When an SII occurs during a budget period, the deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as reported on the relinquishing statement or the available balance in PMS, whichever is less.
- Include a complete face page (PHS 398) for each affected grant showing the transferee as the applicant organization. Each face page must be signed by an AOR at the transferee organization.

- Include a copy of the current negotiated F&A rate agreement for the transferee.

Recipients may choose to submit an electronic application for a successor-in-interest request to satisfy the requirement for the face page(s), confirmation of the transferee's EIN, verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance), and Relinquishing Statement. The electronic application is submitted via Grants.gov using the Parent Funding Opportunity Announcement.

In order to be recognized as the SII, the "new" (transferee) organization must meet each grant program's eligibility requirements; except for grants awarded under the SBIR/STTR programs. See Small Business Innovation Research and Small Business Technology Transfer Programs—Eligibility in IIB for additional guidance. Upon review and acceptance of this information, NIH will revise the NoA(s) to show the transferee as the recipient of record.

For name changes, the recipient's written notification to the lead NIH awarding IC must include the effective date of the change. Revised face pages are not required for name changes because name changes are reported and processed with the next award action (e.g., non-competing continuation award).

8.1.2.9 Deviation from Award Terms and Conditions, including Restrictions in the NoA

NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NoA, including those in the NIHGPS. This includes undertaking any activities disapproved or restricted as a condition of the award.

8.1.2.10 Foreign Component Added to a Grant to a Domestic or Foreign Organization

Adding a foreign component under a grant to a domestic or foreign organization requires NIH prior approval.

8.1.2.11 Provide Subawards Based on Fixed Amounts

With NIH prior approval, a pass-through entity may provide subawards based on fixed amounts (as defined in 2 CFR Part 200.201 and 45 CFR Part 75.201), to which the following conditions apply:

1. The Fixed amount subaward is negotiated using the cost principles (or other pricing information) as a guide. The pass-through entity may use fixed amount subawards if the project scope has specific measurable goals and objectives and if adequate cost, historical, or unit pricing data is available to establish a fixed amount subaward based on a reasonable estimate of actual cost. Payments are based on meeting specific requirements of the subaward. Accountability is based on performance and results. Except in the case of termination before completion of the subaward, there is no governmental review of the actual costs incurred by the non-Federal entity in performance of the subaward. Some of the ways in which the fixed amount subaward may be paid include, but are not limited to:
    a. In several partial payments, the amount of each agreed upon in advance, and the "milestone" or event triggering the payment also agreed upon in advance, and set forth in the subaward;
    b. On a unit price basis, for a defined unit or units, at a defined price or prices, agreed to in advance of performance of the subaward and set forth in the subaward; or,
    c. In one payment at subaward completion.
2. A fixed amount subaward cannot be used in programs which require mandatory cost sharing or match.
3. The non-Federal entity must certify in writing to the pass-through entity at the end of the subaward that the project or activity was completed or the level of effort was expended. If the required level of activity or effort was not carried out, the amount of the subaward must be adjusted.
4. Periodic reports may be established for each fixed amount subaward.
5. Changes in principal investigator, project leader, project partner, or scope of effort must receive the prior written approval of the pass-through entity.

When considering the use of a fix amount subaward, note the distinction between a fixed-amount subaward and a fixed-rate agreement.

In a fixed amount subaward, the total value of the award is negotiated upfront. This requires the pass-through entity to know both the unit price and the total number of units that will be provided. In a fixed-rate agreement, while there is a negotiated cost per unit, e.g. per patient cost in a clinical trial (or participant in a non-Clinical Trial Human Subjects Study), the total amount of the award may be unknown when the agreement is created. Since this type of agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by 2 CFR Part 200.201 and 45 CFR Part 75.201, prior approval is not required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement.

8.1.2.12 Need for Additional NIH Funding without Extension of Budget and Project Period

A request for additional funding for a current budget period to meet increased costs that are within the scope of the approved application, but that were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted, is a non-competing

supplemental application. Such requests must be submitted electronically, for both single and multi-project awards, and are not required to compete with other applications for funding. Other recipient-initiated requests for supplemental funding during a current budget period are considered to change the scope of the approved project and may be required to compete for funding with other applications. When calculating the award for additional funds, NIH will 1) prorate funding if the requested budget is adjusted at the time of award, and 2) use the institution's current F&A rate; i.e., the rate in effect when the new funding is provided.

8.1.2.13 Need for Additional NIH Funding with Extension of the Final Budget Period of a Project Period

A request for a non-competing extension of the final budget period of a project period with a minimal amount of additional funds should be submitted to the GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests usually are for a period of up to 12 months and must be either for work that remains to be completed on the project or to permit orderly phase-out of project activities for which there will be no further NIH support. Resources must be available to continue to support the project. The request must specify the proposed revised ending date and must include justification for both the extension and the additional funds requested. Special justification will be required for an extension that would exceed 12 months. NIH will not approve such requests if the primary purpose of the proposed extension is to permit the use of unobligated balances of funds. All terms and conditions of the award apply during the extended period.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. For NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period with funding.

8.1.2.14 Pre-Award Costs

See Cost Considerations—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs.

8.1.2.15 Rebudgeting of Funds from Trainee Costs

The rebudgeting of amounts previously awarded for trainee costs (stipends, tuition, and fees) to other categories of expense requires NIH prior approval. This excludes trainee travel, which NIH does not consider to be a trainee cost, and training-related expenses (see Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Rebudgeting of Funds in IIB).

8.1.2.16 Rebudgeting of Funds Between Construction and Non-construction Work

Under awards that provide for both construction and non-construction work, NIH prior approval is required to transfer funds between the two types of work.

8.1.2.17 Retention of Research Grant Funds When a Career Development Award is Issued

Funds budgeted under an NIH grant for an individual's salary and fringe benefits, but available as a result of receiving a K award for that individual, may not be used for any other purpose without NIH prior approval.

8.1.3 Requests for Prior Approval

All requests for NIH awarding IC prior approval must be made in writing (including submission by e-mail) to the GMO no later than 30 days before the proposed change, and signed by the AOR. If the request is e-mailed, it must provide evidence of the AOR's approval; a cc to the AOR is not acceptable. A request by a subrecipient for prior approval will be addressed in writing to the recipient. The recipient will promptly review such request and shall approve or disapprove the request in writing. A recipient will not approve any budget or project revision which is inconsistent with the purpose or terms and conditions of the Federal-award to the recipient. If the revision, requested by the subrecipient would result in a change to the recipient's approved project which requires Federal prior approval, the recipient will obtain the awarding IC's approval before approving the subrecipient's request. Failure to obtain required prior approval from the appropriate awarding IC may result in the disallowance of costs, termination of the award, or other enforcement action within NIH's authority. While the PD/PI signature is no longer required as part of the submission to NIH, the recipient must secure and retain such a signature for each prior approval request and make it available to NIH or other authorized DHHS or Federal officials upon request. When multiple PD/PIs are recognized for a particular grant, this requirement applies to all PD/PIs. (See Policies Affecting Applications-Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance).

E-mail requests must be clearly identified as prior approval requests, must reflect the complete grant number in the subject line, and should be sent by the AOR to the GMO that signed the NoA. Contact information is provided on each NoA and is also available in the eRA Commons. E-mail addresses for NIH staff can be also obtained from the NIH Enterprise Directory. E-mail requests must include the name of the recipient, the name of the initiating PD/PI, the PD/PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOR.

The GMO will review the request and provide a response to the AOR indicating the final disposition of the request, with copies to the PD/PI and to the cognizant NIH PO. Only responses provided by the GMO are considered valid. Recipients that proceed on the basis of actions by unauthorized officials do so at their own risk, and NIH is not bound by such responses.

Whenever recipients contemplate rebudgeting or other post-award changes and are uncertain about the need for prior approval, they are strongly encouraged to consult, in advance, with the GMO.

Under a consortium agreement or contract, the prior approval authority usually is the prime recipient. However, the prime recipient may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the NIH grant. If an action by a consortium participant will result in a change in the overall grant project or budget requiring NIH approval, the prime recipient must obtain that approval from NIH before giving its approval to the consortium participant.

8.2 AVAILABILITY OF RESEARCH RESULTS: PUBLICATIONS, INTELLECTUAL PROPERTY RIGHTS, AND SHARING RESEARCH RESOURCES

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also Availability and Confidentiality of Information—Confidentiality of Information—Access to Research Data in Part I for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, apply.

As long as recipients abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR Part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the recipient to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources—"research tools"—may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

8.2.1 Rights in Data (Publication and Copyrighting)

In general, recipients own the rights in data resulting from a grant-supported project. Specific terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable RFA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. For this purpose, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data.

Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages recipients to arrange for publication of NIH-supported original research in primary scientific journals. Recipients also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the recipient from making copies for its own use (as provided in 2 CFR Part 200.315 and 45 CFR Part 75.322). The disposition of royalties and other income earned from a copyrighted work is addressed in Administrative Requirements—Management Systems and Procedures—Program Income.

All recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Each publication, press release, or other document about research supported by an NIH grant must include:

1) An acknowledgment of NIH grant support such as:

"Research reported in this [publication, release] was supported by [name of the Institute, Center, or other funding component] of the National Institutes of Health under grant number [specific NIH grant number in this format: R01GM012345]."

2) A disclaimer that says:

"The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

If the recipient plans to issue a press release about research supported by an NIH grant, it should notify the NIH funding component in advance to allow for coordination. See http://www.nih.gov/news/media_contacts.htm for media contact information.

Publications resulting from work performed under an NIH grant-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports and Administrative Requirements—Closeout—Final Reports—Final Progress Report). When publications are available electronically, the URL or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report. See also NIH Public Access Policy below for additional requirements for publications resulting from NIH funded research.

8.2.2 NIH Public Access Policy

The NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH funded research at the NIH NLM PMC, a free digital archive of full-text biomedical and life sciences journal literature. Under the policy NIH-funded investigators are required by Federal law to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication on or after 4/7/2008, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this policy. Applicants citing articles in NIH applications, proposals, and progress reports that fall under the policy, were authored or co-authored by the applicant and arose from NIH support must include the PMCID or NIHMS ID. The NIHMSID may be used to indicate compliance with the Public Access Policy in applications and progress reports for up to three months after a paper is published. After that period, a PMCID must be provided to demonstrate compliance.

This policy applies to all peer-reviewed articles resulting from research supported in whole or in part with direct costs from NIH, including research grant and career development awards, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, SBIR/STTR awards, and NIH intramural research studies.

Additional information can be found at: http://publicaccess.nih.gov/.

8.2.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can

impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of recipients and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act. See the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page.

Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

To provide further clarification of the NIH policy on disseminating unique research resources, NIH published *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999. This document will assist recipients in determining reasonable terms and conditions for disseminating and acquiring research tools.

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding IC, the recipient also must provide a copy of documents or a sample of any material developed under an NIH grant award. The recipient may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see Administrative Requirements—Management Systems and Procedures—Program Income).

To facilitate the availability of unique or novel materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories and should ensure that those entities distribute them in a way that is consistent with the above referenced *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

8.2.3.1 Policy for Data Management and Sharing (DMS Policy)

NIH has a longstanding commitment to making the results and outputs of NIH-funded research available to the public through effective and efficient data management and data sharing practices, Data sharing enables researchers to rigorously test the validity of research findings, strengthen analyses through combined datasets, reuse hard-to-generate data, and explore new frontiers of discovery. In addition, NIH emphasizes the importance of good data management practices, which provide the foundation for effective data sharing and improve the reproducibility and reliability of research findings. NIH encourages data management and data sharing practices consistent with the FAIR (Findable, Accessible, Interoperable, and Reusable) data principles.

Effective January 25, 2023, NIH will require recipients, when applicable, to submit a Data Management and Sharing Plan (Plan) with their grant application outlining how scientific data and any accompanying metadata will be managed and shared.

8.2.3.2 Data Management and Sharing Cost

All allowable Data Management and Sharing costs in budget requests must be incurred (e.g., curation fees, data repository fees) during the performance period, even for scientific data and metadata preserved and shared beyond the award period. Consistent with 45 CFR 75.403 and the NIH Grants Policy Statement Section 7.4, budget requests must not include infrastructure costs that are included in institutional overhead (e.g., Facilities and Administrative costs) or costs associated with the routine conduct of research. Costs associated with collecting or otherwise gaining access to research data (e.g., data access fees) are considered costs of doing research and should not be included in scientific data management and sharing budgets. Costs may not be double charged or inconsistently charged as both direct and indirect costs.

Applicants may request data management and sharing costs that are allowable and reasonable when associated with (1) Curating data and developing supporting documentation, including formatting data according to accepted community standards; de-identifying data; preparing metadata to foster discoverability, interpretation, and reuse; and formatting data for transmission to and storage at a selected repository for long-term preservation and access. (2) Local data management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository). (3) Preserving and sharing data through established repositories, such as data deposit fees necessary for making data available and accessible. For example, if a Data Management and Sharing Plan proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, the cost for the entire 10-year period must be paid prior to the end of the period of performance. If the Plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

8.2.3.3 Timing for Sharing Data

Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first. Researchers are encouraged to consider relevant requirements and expectations (e.g., data repository policies, award record retention requirements, journal policies) as guidance for the minimum time frame that scientific data should be made available, which researchers may extend.

8.2.3.4 Sharing Model Organisms

All applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

This expectation is for **all** applications where the development of model organisms is anticipated, regardless of funding amount.

For additional information on this policy, see the NIH Scientific Data Sharing website.

8.2.3.5 Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)

The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports NIH's

mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health.

The GDS Policy, an extension of the 2008 NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (the NIH GWAS Policy), applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. For the purposes of this Policy, the genome is the entire set of genetic instructions found in a cell and large-scale genomic data include GWAS, single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the GDS Policy provides examples of genomic research projects that are subject to the Policy and the timeline for submission and sharing of data from such projects.

The GDS Policy became effective on January 25, 2015 for grant applications with due dates on or after that date. Research that was initiated prior to the effective date of the GDS Policy will continue to operate under the terms of the policies that were in effect when the research began, such as the NIH GWAS Policy, however, NIH strongly encourages investigators to comply with the expectations outlined in the GDS Policy. All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to describe plans for sharing genomic data in the Data Management and Sharing (DMS) Plan submitted with the application, and not in a separate GDS Plan or at Just-in-Time, consistent with the changes described in 8.2.3.1 Policy for Data Management and Sharing. For guidance on development a DMS plan that meets the requirements of the DMS plan that meets the requirements of the GDS policy, see the NIH Scientific Data Sharing website.

Investigators who wish to use cloud computing for storage and analysis will need to indicate in their Data Access Request (DAR) that they are requesting permission to use cloud computing and identify the cloud service provider or providers that will be employed. They also will need to describe how the cloud computing service will be used to carry out their proposed research.

As with data stored in institutional systems, the institution's signing official, Program Director/Principal Investigator, IT Director, and any other personnel approved by NIH to access the data are responsible for ensuring the protection of the data. The institution, not the cloud service provider, assumes responsibility for any failure in the oversight of using cloud computing services for controlled-access data.

The NIH Security Best Practices for Controlled Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy has been updated to include best practices for cloud computing. The Model Data Use Certification has also been updated and is available at http://gds.nih.gov/pdf/Model_DUC.pdf.

For additional information including best practices see: Genomic Data Sharing Policy. Questions about the GDS policy can be e-mailed to GDS@mail.nih.gov.

8.2.4 Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212; Executive Order 12591; 37 C.F.R. 401 et al; updated April 14, 2018.) provides NIH funding recipients incentives to promote the utilization of inventions conceived or reduced to practice (Subject Invention) in the performance of federally supported research and development. Unless waived by NIH or the funding agreement is for educational purposes, e.g. fellowships, training grants or certain types of career development awards, the Bayh-Dole Act applies to all NIH research and development funding granted to commercial organizations regardless of size and all non-profit entities. (See 2 CFR Part 200, 45 CFR Part 75 and 37 CFR Part 401.1(b)).

To retain rights and title to Subject Inventions, the NIH funding recipient must comply with the Bayh-Dole statute and implementing regulations that ensure the Invention will be brought to practical applic-

ation while protecting certain rights of the Federal government. The compliance actions required by the Bayh-Dole Act are summarized below at Exhibit 8.

Failure of the recipient to comply with any of the Bayh-Dole regulations cited at 37 CFR Part 401 or other requirements may result in the loss of patent rights or the suspension, termination or withholding of NIH funding support. See also Section 8.5.2 for additional remedies for noncompliance of the Bayh-Dole Act.

All Bayh-Dole compliance actions are required to be submitted to NIH by using the iEdison data base (See 37 CFR Part 401.16). All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to the Division of Extramural Inventions and Technology Resources, OPERA/OER at edison@nih.gov.

Exhibit 8. Extramural Invention Reporting Compliance Responsibilities

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Employee Agreement to Disclose All Subject Inventions	Recipient employees working under a federal funding award (other than clerical and nontechnical employees) must sign an agreement with the recipient organization. This agreement requires the Recipient employee to: (1) disclose promptly in writing to personnel identified as responsible for the administration of patent matters each Subject Invention made under NIH funding; (2) assign to the Recipient the entire right, title and interest in and to each Subject Invention made under the funding agreement; (3) execute all papers necessary to file patent applications on Subject Inventions; and, (4) establish the government's right in the Subject Inventions.	Before a Recipient or a consortium employee participates in NIH-funded research and development.	401.14(f)(2)
Consortium Participant Rights in Inventions	All consortium participants, regardless of tier, for experimental, developmental or research work retain all rights and obligations provided to the Consortium Participant in the NIH funding agreement.	At the time of issuance of a consortium agreement, recipient must include in all consortium agreements, regardless of tier, for experimental, development, or research work 37 CFR Part 401 *et seq* suitably modified to identify the parties and the rights and obligations awarded to the contractor.	401.14(g)(1) 401.14(g)(2) 401.14(g)(3)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Invention Disclosure	**The term "Subject Invention"** means any invention of a recipient/consortium participant conceived or first actually reduced to practice in the performance of work under a funding agreement. The recipient must submit to NIH a disclosure for all Subject Inventions. There is no single format for disclosing the invention to NIH. However, the disclosure of the Subject Invention must include: a detailed technical description of the invention conveying a clear understanding of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention; the names of all inventors; title of the Subject Invention; all federal funding agreement numbers; date of disclosure of the Subject Invention from the researcher or inventor to the Recipient; and whether a manuscript describing the invention was submitted, accepted and/or published.	Within 2 months of the inventor's disclosure to the recipient organization.	401.14(a)(2) 401.14(c)(1)
Government Assignment to Recipient of Rights in Invention of Government Employee	Disclosure to NIH that a federal employee is a co-inventor on a Subject Invention.	Within 2 months of receipt of the initial invention report.	401.14(f)(2) 401.10

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Acceptance of Manuscript following Submission of Initial Invention Disclosure	The recipient needs to promptly notify NIH of the acceptance of any manuscript describing the Subject Invention.	Promptly following the acceptance of a manuscript describing a Subject Invention.	401.14(c)(1)
Election of Title to a Subject Invention	The recipient must notify NIH of its decision to retain title to a Subject Invention and any associated patent rights. Election of title is made before the filing of an **Initial Patent Application**. **Statutory Period** is defined as the one-year period before the effective filing date of a claimed invention during which exceptions to prior art exist per 35 U.S.C. 102 (b) as amended by the Leah-Smith American Inventions Act, Public Law 112-29.	Within 2 years of the disclosure of the invention to NIH. In any case where a patent, a printed publication, public use, sale or other availability to the public has initiated the one-year **Statutory Period** wherein valid patent protection can still be obtained in the United States, the period for election of title is shortened by NIH to a date that is no more than 60 days prior to the end of the statutory period.	401.14(b) 401.14(c)(2) 401.2(n)
Confirmatory License	For each Subject Invention, the recipient must provide a license to NIH confirming the rights the Government has throughout the world in the Subject Invention. When a confirmatory license is filed on the **Initial Patent Application** the license applies to all subsequent patent applications linked in the patent family.	When the **Initial Patent Application** is filed.	401.14(f)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Government Support Clause	The recipient must include, within the specification of all United States patent applications and any patent issuing thereon covering a Subject Invention, the following statement, "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention."	Must be included within the specifications of any United States patent applications and any patent(s) issuing thereon covering a Subject Invention.	401.14(f)(4)
Patent Applications and Issued Patents	The recipient must inform NIH of the filing date of its **Initial Patent Application**, the **Initial Patent Application** number and title and all subsequently filed patent applications. **Initial Patent Application** is defined as the first provisional or nonprovisional U.S. national application for patent as defined in 37 CFR Part 1.9(a)(2) and (3), respectively, the first international application filed under the Patent Cooperation Treaty as defined in 37 CFR Part 1.9(b) that designates the United States, or the first application for a Plan Variety Protection certificate, as applicable, a non-provisional U.S. national application for patent as defined in 37 CFR Part 1.9(a)(3).	Within 1 year after election of title, or, if earlier, prior to the end of any Statutory Period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use, unless there is an extension of time granted by NIH.	401.14(c)(3) 401.14.(f)(6) 401.2(n)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Notification to NIH to Not to Continue Prosecution	Notify NIH of any decision to: not to continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a part to, or take action in a trial proceeding before the Patent Trial and Appeals Board of the U.S. Patent and Trademark Office including but not limited to post-grant review, review of a business method patent, *inter partes* review, and deviation proceeding; or to request, be a part to, or take action in a non-trial submission of art or information at the U.S. Patent and Trademark Office, including but not limited to a pre-issuance submission, a post-issuance submission, and supplemental examination.	Notify NIH no less than 60 days prior to taking any action defined under "Action Required."	401.14(f)(3)
Assignment of Rights to Third Party	If the recipient is a non-profit organization, it must request NIH prior approval to assign a Subject Invention or U.S. patent rights to any third party, including the inventor(s). Recipients that are commercial entities (including small businesses) do not need to request approval for the assignment of a Subject Invention or U.S. patent rights to any third party.	Recipient must submit a Third-Party Waiver Request or an Inventor Waiver Request and must have NIH approval before any rights of the recipient are transferred or assigned.	401.10 401.14(k)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Preference for United States Industry	Recipient cannot grant to any person, unless approved by NIH in advance, the exclusive right to use or sell any Subject Invention in the United States unless any such product embodying the Subject Invention or produced through the use of the Subject Invention is manufactured substantially in the United States.	For a waiver of this compliance requirement, a request is required to NIH providing specific details and reasons why the Subject Invention cannot be substantially manufactured in the United States.	401.14(i)
Issued Patent	Recipient must notify NIH of the date a patent is issued, patent number, and the expiration date of the issued patent.	When patent is issued.	401.5(f)(2)
Extension of Time to Disclose a Subject Invention	The recipient may request for NIH's approval for an extension of time to disclose a Subject Invention.	Not less than 30 days in advance of the 60-day disclosure reporting deadline.	401.14(c)(5)
Extension of Time to Elect Title to a Subject Invention	Recipient may request with justification, NIH's approval of a request for an extension of up to 2 years to elect title to a Subject Invention.	As needed before the expiration of the time allowed.	401.14(c)(5)
Extension of Time to File a Patent Application	The recipient may request, subject to NIH's approval, an extension time up to 1 year to file a patent application. The request must include details of why an extension is needed.	As needed before the expiration of the time allowed.	401.14(c)(5)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Extension of Time to File a Non-provisional Patent Application following the Filing of a Provisional Application as the Initial Patent Application	When a recipient requests an extension of time for filing a non-provisional application, after filing a provisional application as an **Initial Patent Application**, a 1-year extension will be granted unless NIH notifies the recipient within 60 days of receiving the request. Recipient must submit this request citing an extension of time pursuant to 401.14(c)(5). No additional details for the request are required.	As needed before the expiration of the time allowed.	401.14(c)(5)
Invention Utilization Report	The recipient must submit an annual utilization report with information about the status of commercialization of any Subject Invention for which title has been elected.	Annually, based on the fiscal year of the recipient.	401.14(h)
Annual Invention Statement	The recipient must indicate any inventions made during the previous budget period in Section C of the Research Performance Progress Report (RPPR).	Part of all competing applications and non-competing continuation progress reports.	SF424, (R&R) PHS 2590, RPPR
Final Invention Statement and Certification	The recipient must submit to the NIH awarding IC CGMO through the eRA Closeout Module a summary of all inventions made during the entire term of each grant award.	Within 120 days after the project period (competitive segment) ends.	401.14(f)(5)

8.2.5 Interim Research Products

Interim Research Products are complete, public research products that are not final. A common form is the preprint, which is a complete and public draft of a scientific document. Interim research products are effective ways for NIH funded scientists to speed dissemination, establish priority, obtain feedback, and reduce bias. They may also be cited in applications for NIH funding.

NIH intends to maximize impact of interim research products that are developed with NIH funds. Therefore, NIH expects recipients to ensure a high level of public access to NIH supported interim products.

To facilitate text mining and other analysis of these products as data, NIH expects standardized terms of use. NIH also expects recipients will adhere to other norms of responsible scientific communication.

Specifically, to claim an interim research product as a product of an NIH award, NIH expects that the recipient will:

- Make the product publicly available. To maximize the impact of an interim research product, NIH strongly encouragesrecipients to select a Creative Commons Attribution (CC-BY) license or dedicate their work to the public domain.
- In the text of the document:
    - Acknowledge NIH funding in accordance with NIH GPS Section 8.2.1
    - Clearly state that the work is not peer-reviewed
    - Declare any competing interests, as an author would do for any journal article

8.3 MANAGEMENT SYSTEMS AND PROCEDURES

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients may use their existing systems to manage NIH grant funds and activities as long as they are consistently applied regardless of the source of funds and meet the standards and requirements set forth in 2 CFR Part 200 and 45 CFR Part 75 and the NIHGPS. NIH may review the adequacy of those systems and may take appropriate action, as necessary, to protect the Federal government's interests, including, but not limited to, the use of specific terms and conditions. NIH also will oversee the recipient's systems as part of its routine post-award monitoring. The recipient's systems also are subject to audit (see Administrative Requirements—Monitoring—Audit).

NIH seeks to foster within recipient organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; performance assessment; administrative simplifications; information sharing; management controls and other internal controls.

Recipient organizations must establish and maintain effective internal controls to provide reasonable assurance that they are in compliance with Federal statutes, regulations, and terms and conditions of award (45 CFR 75.303(a) and (b)). They must evaluate and monitor their compliance with statutes, regulations, and terms and conditions (45 CFR 75.303(c)), and they must take prompt action when instances of noncompliance are identified (45 CFR 75.303(d)).

Recipient organizations' internal controls should be in compliance with guidance in "Standards for Control in the Federal Government." (45 CFR 75.303(a)). Thus, recipient organizations are expected to establish codes of conduct which define expectations of integrity and ethical values and criteria of competence of personnel involved in the work supported by NIH grant funds. Codes of conduct should articulate expectations to assure compliance with terms and conditions of award, including but not limited to, providing true, complete, and accurate information on application documents (2.3.7.6); assuring work environments are free of discriminatory harassment and are safe and conducive to high-quality work (4); and meeting applicable public policy requirements (4.1).

8.3.1 Financial Management System Standards

Recipients are required to meet the standards and requirements for financial management systems set forth or referenced in 2 CFR Part 200.302 and 45 CFR Part 75.302, as applicable. The standards and

requirements for a financial management system are essential to the grant relationship. NIH cannot support the research unless it has assurance that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded.

Recipients must have in place accounting and internal control systems that provide for appropriate monitoring of grant accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify large unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds. Recipients must notify NIH when problems are identified.

A recipient's failure to establish adequate control systems constitutes a material violation of the terms of the award. Under these circumstances, NIH may include specific conditions on awards or take any of the range of actions specified in Administrative Requirements—Enforcement Actions, as necessary and appropriate.

8.3.2 Program Income

Program income is gross income—earned by a recipient, a consortium participant, or a contractor under a grant—that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed; charges for the use or rental of real property, equipment or supplies acquired under the grant; the sale of commodities or items fabricated under an award; charges for research resources; registration fees for grant-supported conferences, and license fees and royalties on patents and copyrights. (Note: Program income from license fees and royalties from copyrighted material, patents, and inventions is exempt from reporting requirements unless otherwise specified in the terms and conditions of award.) The requirements for accountability for these various types of income under NIH grants are specified in this subsection. Accountability refers to whether NIH will specify how the income is to be used and whether the income needs to be reported to NIH and for what length of time. Unless otherwise specified in the terms and conditions of the award, NIH recipients are not accountable for program income accrued after the period of grant support.

NIH applies the additive alternative to all recipients, including commercial entities, unless there is a concern with the recipient or activity and NIH uses specific terms and conditions, or the program requires a different program income alternative. NIH may require a different use of program income if a recipient has deficient systems; if the PD/PI has a history of frequent, large annual unobligated balances on previous grants; or if the PD/PI has requested multiple extensions of the final budget period of the project period. Regardless of the alternative applied, program income may be used only for allowable costs in accordance with the applicable cost principles and the terms and conditions of the award. Each NoA will indicate the allowable treatment of program income. Program income alternatives and their usage are noted below in Exhibit 9.

Consortium agreements and contracts under grants are subject to the terms of the agreement or contract with regard to the income generated by the activities, but the terms specified by the recipient must be consistent with the requirements of the grant award. Program income must be reported by the recipient as discussed in this subsection.

8.3.2.1 Reporting Program Income

The amount of program income earned and the amount expended must be reported on the appropriate annual financial report, currently the FFR. Any costs associated with the generation of the gross amount of program income that are not charged to the grant should be deducted from the gross program income earned, and the net program income should be the amount reported. Program income must be reported in the Program Income section of the FFR (lines 10 L – O). (See Administrative Requirements—

Monitoring—Reporting—Financial Reporting.) For awards under SNAP, the amount of program income earned must be reported in the non-competing continuation progress report.

Income resulting from royalties or licensing fees is generally exempt from reporting as program income.

When applicable, income earned from the sale of equipment must be reported on the FFR for the period in which the proceeds are received in accordance with the reporting requirements for the program income alternative specified. Amounts due NIH for unused supplies must be reflected as a credit to the grant on the FFR using line 10 m.

Reporting requirements for accountable income accrued after grant support ends will be specified in the NoA.

Exhibit 9. Use and Applicability of Program Income Alternatives

Program income alternative	Use of program income	Applicability
Additive Alternative	Added to funds committed to the project or program and used to further eligible project or program objectives.	Applies to all NIH awards unless there is a concern with the recipient or activity or the program requires a different alternative.
Deductive Alternative	Deducted from total allowable costs of the project or program to determine the net allowable costs on which the Federal share of costs will be based.	Available for use by NIH programs on an exception basis.
Combination Alternative	Uses all program income up to (and including) $25,000 as specified under the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative.	Available for use by NIH programs on an exception basis.
Matching Alternative	Used to satisfy all or part of the non-Federal share of a project or program.	Available for use by NIH programs that require matching.

8.3.2.2 Sale of Real Property, Equipment, and Supplies

The requirements that apply to the sale of real property are addressed in the Construction Grants chapter. For equipment and supplies purchased under NIH grants for basic or applied research by non-profit institutions of higher education or non-profit organizations whose principal purpose is the conduct of scientific research, the recipient is exempt from any requirement to account to NIH for proceeds from the sale of the equipment or supplies; however, NIH has certain rights with respect to such property as specified in Administrative Requirements—Management Systems and Procedures—Property Management System Standards.

All other types of grants and recipients are subject to the requirements specified in 2 CFR Part 200.313 and 45 CFR Part 75.320 and 200.439 and 45 CFR Part 75.439 if title to the equipment vests in the recipient rather than in NIH. If the grant-supported project or program for which equipment was acquired is still receiving NIH funding at the time of sale, the recipient must credit the NIH share of the proceeds to the grant and use that amount under the deductive alternative for program income. If the recipient is no longer receiving NIH grant support, the amount due should be paid in accordance with instructions from

NIH. These grants and recipients also are subject to the requirements in 2 CFR Part 200.314 and 45 CFR Part 75.321 and 200.453 and 45 CFR Part 75.453 with respect to the use or sale of unused supplies. If the recipient retains the supplies for use on other than federally sponsored activities, an amount is due NIH as if they were sold.

8.3.2.3 Royalties and Licensing Fees from Copyrights, Inventions, and Patents

NIH recipients do not have to report program income resulting from royalties or licensing fees from sale of copyrighted material unless specific terms and conditions of the award provide otherwise. The NoA may include specific terms and conditions if commercialization of an invention is an anticipated outcome of a research project.

However, the regulations implementing the Bayh-Dole Act (37 CFR Part 401.14(h)) require reporting of income resulting from NIH-funded inventions and patents. Specifically, as part of the annual invention utilization report, recipients must report income generated by all subject inventions to which title has been elected and by inventions such as research tools that have been licensed but not patented (see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources and Administrative Requirements—Monitoring—Reporting).

8.3.3 Property Management System Standards

Generally, recipients may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH grant funds, provided they observe the regulatory requirements in 2 CFR Parts 200.310 through 200.316, and 45 CFR Part 75.307 through 45 CFR Part 75.323, as applicable, and the following. State governments will use, manage, and dispose of equipment acquired under a grant in accordance with state laws and procedures as specified in 45 CFR Part 92.32.

The dollar threshold for determining the applicability of several of the requirements in those regulations is based on the unit acquisition cost of an item of equipment. As defined in 2 CFR Part 200.1 and 45 CFR Part 75.2, the acquisition cost of an item of equipment to the recipient includes necessary modifications and attachments that make it usable for the purpose for which it was acquired or fabricated. When such accessories or attachments are acquired separately and serve to replace, enhance, supplement, or otherwise modify the equipment's capacity and they individually meet the definition of equipment (see Glossary in Part I), any required NIH prior approval for equipment must be observed for each item. However, the aggregate acquisition cost of an operating piece of equipment will be used to determine the applicable provisions of 2 CFR Part 200.313 and 45 CFR Part 75.320. If property is fabricated from individual component parts, each component must itself be classified as equipment if it meets the definition of equipment. In this case, the aggregate acquisition cost of the resulting piece of equipment will determine the appropriate accountability requirements in 2 CFR Part 200.313 and 45 CFR Part 75.320.

Recipients are required to be prudent in the acquisition of property under a grant-supported project. It is the recipient's responsibility to conduct a prior review of each proposed property acquisition to ensure that the property is needed and that the need cannot be met with property already in the possession of the organization. If prior approval is required for the acquisition, the recipient must ensure that appropriate approval is obtained in advance of the acquisition. The recipient also must follow appropriate procurement procedures in acquiring property as specified in Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements.

Recipients of NIH grants other than Federal institutions cannot be authorized to use Federal supply sources.

8.3.3.1 Real Property

See Construction Grants—Real Property Management Standards in IIB for requirements that apply to the acquisition, use, and disposition of real property. Fixed equipment that is part of a construction grant is subject to those requirements.

8.3.3.2 Equipment and Supplies

In general, title to equipment and supplies acquired by a recipient with NIH funds vests in the recipient upon acquisition, subject to property management requirements of 2 CFR Parts 200.310 and 45 CFR Part 75.317, 200.313 and 45 CFR Part 75.320, 200.314 and 45 CFR Part 75.321, and 2 CFR Part 200.316 and 45 CFR Part 75.323. Limited exceptions to these general rules are States, which may use, manage, and dispose of equipment acquired under a grant in accordance with State laws and procedures, and certain research grant recipients with exempt property (see 2 CFR Part 200.317 and 45 CFR Part 75.326). These requirements do not apply to equipment for which only depreciation or use allowances are charged, donated equipment, or equipment acquired primarily for sale or rental rather than for use.

8.3.3.2.1 Exempt Property

Under the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6306, NIH may permit non-profit institutions of higher education and non-profit organizations whose primary purpose is the conduct of scientific research to obtain title to equipment and supplies acquired under grants for support of basic or applied scientific research without further obligation to the Federal government. However, there is one exception: NIH has the right to require transfer of title to equipment with an acquisition cost of $5,000 or more to the Federal government or to an eligible third party named by the NIH awarding IC under the conditions specified in 2 CFR Part 200.312 and 45 CFR Part 75.319. NIH may exercise this right within 120 days of the completion or termination of an award or within 120 days of receipt of an inventory, as provided in 2 CFR Part 200.313 and 45 CFR Part 75.320, whichever is later.

8.3.3.2.2 Nonexempt Property

All other equipment and supplies acquired under all other NIH grant-supported projects by any other type of recipient are subject to the full range of acquisition, use, management, and disposition requirements of 2 CFR Part 200.313 and 45 CFR Part 75.320 and 2 CFR Part 200.314 and 45 CFR Part 75.321. Property acquired or used under an NIH grant-supported project, including any federally owned property, also is subject to the requirements for internal control specified in 2 CFR Part 200.303 and 45 CFR Part 75.303. Pursuant to 2 CFR Part .316, equipment (and intangible property and debt instruments) acquired with, or improved with, NIH funds must not be encumbered without NIH approval.

The recipient's management system for equipment must meet the requirements of 2 CFR Part 2.313, which include the following:

- Records that adequately identify (according to the criteria specified in the regulations) items of equipment owned or held by the recipient and state the current location of each item.
- A physical inventory of the equipment, at least once every 2 years, to verify that the items in the records exist and either are usable and needed or are surplus (a statistical sampling basis is acceptable).
- Control procedures and safeguards to prevent loss, damage, and theft.
- Adequate maintenance procedures to keep the equipment in good condition.
- Proper sales procedures when the recipient is authorized to sell the equipment.

For items of equipment having a unit acquisition cost of $5,000 or more, NIH has the right to require transfer title to the equipment to the Federal government or to an eligible third party named by the NIH awarding IC under the conditions specified in 2 CFR Part 200.313 and 45 CFR Part 75.320. Such transfer shall be subject to the following standards: (1) The equipment shall be appropriately identified in the award or otherwise made known to the recipient in writing. (2) The awarding IC may require submission of a final inventory that lists all equipment acquired with NIH funds and federally-owned equipment. (3) If the awarding IC fails to issue disposition instructions within 120 calendar days after receipt of the inventory or if so instructed, the recipient shall sell the equipment and reimburse the HHS awarding agency an amount computed by applying to the sales proceeds the percentage of HHS share in the cost of the original project or program. However, the recipient shall be permitted to deduct and retain from the NIH share $500 or ten percent of the proceeds, whichever is less, for the recipient's selling and handling expenses. If the recipient is instructed to ship the equipment elsewhere, the recipient shall be reimbursed by the awarding IC an amount which is computed by applying the percentage of the recipient's share in the cost of the original project or program to the current fair market value of the equipment, plus any reasonable shipping or interim storage costs incurred. If the recipient is instructed to otherwise dispose of the equipment, the recipient will be reimbursed by the HHS awarding agency for such costs incurred in its disposition. If the recipient's project or program for which or under which the equipment was acquired is still receiving support from the same HHS program, and if the HHS awarding agency approves, the net amount due may be used for allowable costs of that project or program. Otherwise the net amount must be remitted to the HHS awarding agency by check. This right applies to nonexempt property acquired by all types of recipients, including Federal institutions, under all types of grants under the stipulated conditions.

If there is a residual inventory of unused supplies exceeding $5,000 in aggregate fair market value upon termination or completion of the grant and if the supplies are not needed for other federally sponsored programs or projects, the recipient may either retain them for use on other than federally sponsored activities or sell them, but, in either case, the recipient must compensate the NIH awarding IC for its share as a credit to the grant.

Recipients of NIH grants must not use equipment acquired with grant funds to provide services for a fee to compete unfairly with private companies that provide equivalent services, unless the terms and conditions of the award provide otherwise.

8.3.3.2.3 Revocable License

As permitted under Federal property management statutes and regulations and NIH property management policies, federally owned tangible personal property may be made available to recipients under a revocable license agreement. The revocable license agreement between NIH and the recipient provides for the transfer of the equipment for the period of grant support under the following conditions:

- Title to the property remains with the Federal government.
- NIH reserves the right to require the property to be returned to the Federal government should it be determined to be in the best interests of the Federal government to do so.
- The use to which the recipient puts the property does not permanently damage it for Federal government use.
- The property is controlled and maintained in accordance with the requirements of 48 CFR Part 45.5 (the FAR).

8.3.4 Procurement System Standards and Requirements

8.3.4.1 General

Recipients may acquire a variety of goods or services in connection with a grant-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. States may follow the same policies and procedures they use for procurements from non-Federal funds and ensure that every purchase order or other contract includes any clauses required by 2 CFR Part 200.327. All other recipients must follow the requirements in 2 CFR Part 200.317 through 200.327 and 45 CFR Part 75.326 for the purchase of goods or services through contracts under grants. The requirements for third-party activities involving programmatic work are addressed under Consortium Agreements chapter in IIB.

A contract under a grant must be a written agreement between the recipient and the third party. The contract must, as appropriate, state the activities to be performed; the time schedule; the policies and requirements that apply to the contractor, including those required by 2 CFR Part 200, Appendix II - Contract Provisions for Non-Federal Entity Contracts Under Federal Awards and other terms and conditions of the grant (these may be incorporated by reference where feasible); the maximum amount of money for which the recipient may become liable to the third party under the agreement; and the cost principles to be used in determining allowable costs in the case of cost-type contracts. The contract must not affect the recipient's overall responsibility for the direction of the project and accountability to the Federal government. Therefore, the agreement must reserve sufficient rights and control to the recipient to enable it to fulfill its responsibilities.

When a recipient enters into a service-type contract in which the term is not concurrent with the budget period of the award, the recipient may charge the costs of the contract to the budget period in which the contract is executed even though some of the services will be performed in a succeeding period if the following conditions are met:

- The NIH awarding IC has been made aware of this situation either at the time of application or through post-award notification.
- The project has been recommended for a project period extending beyond the current year of support.
- The recipient has a legal commitment to continue the contract for its full term.

However, costs will be allowable only to the extent that they are for services provided during the period of NIH support. To limit liability if continued NIH funding is not forthcoming, it is recommended that recipients insert a clause in such contracts of $100,000 or less stipulating that payment beyond the end of the current budget period is contingent on continued Federal funding. The contract provisions prescribed by 2 CFR Part 200, Appendix II - Contract Provisions for Non-Federal Entity Contracts Under Federal Awards, paragraph B specify termination provisions for contracts in excess of $100,000.

8.3.4.2 Approval Requirements

The procurement standards in 2 CFR Part 200.325 and 45 CFR Part 75.333 allow NIH to require approval of specific procurement transactions under the following circumstances (and provide a mechanism for governmental recipients to be exempt from this type of review):

- A recipient's procurement procedures or operations do not comply with the procurement standards required by those regulations.

- The procurement is expected to exceed the "simplified acquisition threshold" (currently $250,000 per OMB memo M-18-18) (formerly the "small purchase threshold") established by the Federal Property and Administrative Services Act, as amended, and is to be awarded without competition or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the simplified acquisition threshold specifies a "brand name" product.
- A proposed award over the simplified acquisition threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.

When NIH prior approval is required, the recipient must make available sufficient information to enable review. This may include, at NIH discretion, presolicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the applicant or recipient or may be conditioned on the receipt of additional information. Any resulting NIH approval does not constitute a legal endorsement of the business arrangement by the Federal government nor does such approval establish NIH as a party to the contract or any of its provisions.

8.3.4.3 Contracting with Small Businesses, Minority-Owned Firms, and Women's Business Enterprises

Recipients must make positive efforts to use small businesses, minority-owned firms, and women's business enterprises as sources of goods and services whenever possible. Recipients should take the steps outlined in the applicable administrative requirements (2 CFR Part 200.321 and 45 CFR Part 75.330) to implement this policy.

8.3.4.4 Domestic Preferences for Procurements

As appropriate and to the extent consistent with law, the non-Federal entity should, to the greatest extent practicable under a Federal award provide a preference for the purchase, acquisition, or use of goods, products, or materials produced in the United States (including but not limited to iron, aluminum, steel, cement, and other manufactured products). The requirements of this section must be included in all subawards including all contracts and purchase orders for work or products under this award. See 2 CFR Part 200.322.

8.4 MONITORING

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with NIH requirements. However, to fulfill their role in regard to the stewardship of Federal funds, NIH awarding ICs monitor their grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to NIH. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the grant is administratively closed out and NIH is no longer providing active grant support (see Administrative Requirements—Closeout).

8.4.1 Reporting

NIH requires that recipients periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Recipients also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and closeout documents (final grant progress reports and final invention statements and certifications). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to OFM (see Financial Reports below) through PMS unless otherwise indicated in the award's terms and conditions.

Recipients are allowed a specified period of time to submit required financial and final progress reports (see 2 CFR 200.328 and 45 CFR Part 75.341 and 2 CFR Part 200.329 and 45 CFR Part 75.342, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

8.4.1.1 Non-Competing Continuation Progress Reports

Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The Research Performance Progress Report (RPPR) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information.

NIH requires the use of the RPPR for all Type 5 progress reports, including accessing the Human Subjects System link in the RPPR, if applicable, that will allow reporting of inclusion enrollment data.

Recipients should routinely query and review the list of pending grant progress reports and due dates available at the NIH web site. Late submission of a grant progress report will result in delaying the issuance and funding of the non-competing continuation award and may result in a reduced award amount.

Recipients also have an obligation to submit a complete and accurate progress report. NIH program or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information will result in a delayed award. Incomplete or inadequate progress reports may result in a delay of continued support.

The progress report for the final budget period of a competitive segment for which a competing continuation application is submitted will be part of that application; however, if an award is not made or the recipient does not submit an application for continued support, a final RPPR is required (see Final Research Performance Progress Report).

The NIH awarding IC will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, major alteration and renovation, and non-construction activities.

8.4.1.1.1 Requirement for Commons ID

For progress reports using the RPPR, the Commons ID requirement is part of the Participants Section and is required for the PD/PI(s) and those who worked on the project in a postdoctoral role. This could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

For undergraduate and graduate students supported on a particular research grant, a Commons ID is required. Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now. For graduate students, this could include project roles of graduate research assistant or graduate student.

When an individual is assigned the Undergraduate, Graduate Student, and/or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482.

Note, the Graduate Student and Postdoctoral eRA Commons Roles should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions. Nor should they be used for individuals supported on institutional training grants and reported using xTrain; the Trainee Role must continue to be used for those individuals.

A Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

8.4.1.1.2 Expectation for Institutions to Develop Individual Development Plans for Graduate Students and Postdoctoral Researchers

In an effort to assist graduate students and post-doctoral researchers in achieving their career goals and become contributing members of the biomedical workforce, NIH encourages recipients to develop an institutional policy requiring that an Individual Development Plan (IDP) be implemented for every graduate student and postdoctoral researcher supported by any NIH grant and reportable on the progress report, regardless of the type of NIH grant that is used for support. This is an expectation that should be broadly implemented by institutions for all graduate students and postdoctoral researchers supported by NIH. The actual reporting of the implementation of this expectation is in the RPPR; recipients must report in RPPR *Section B. Accomplishments*, Question B.4 the use of the IDP for graduate students and/or postdoctoral researchers included in RPPR *Section D*. Participants or on a Statement of Appointment Form (PHS 2271). Do not include the actual IDP; instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.

8.4.1.2 Streamlined Non-Competing Award Process

SNAP includes a number of provisions that modify annual progress reports, NoAs, and financial reports.

The NoA will specify whether an award is subject to SNAP. Awards routinely included in SNAP are “K” awards and “R” awards, except R35. Awards excluded from SNAP are those that generally do not have the authority to automatically carry over unobligated balances (centers; cooperative agreements, Kirschstein-NRSA institutional research training grants, non-Fast Track Phase I SBIR and STTR awards), clinical trials (regardless of activity code), P01, R35, and awards to individuals. However, these grants can be included in SNAP on a grant-specific basis. In addition, specific awards may be excluded from SNAP if:

- they require close project monitoring or technical assistance, e.g., high-risk recipients, certain large individual or multi-project grants, or grants with significant unobligated balances, or
- the recipient has a consistent pattern of failure to adhere to appropriate reporting or notification deadlines.

8.4.1.2.1 Modified Annual Progress Reports

While a modified, streamlined, progress report is still a feature of grants awarded under the SNAP authorities, a streamlined version of the RPPR has replaced the eSNAP module in the eRA Commons. For all SNAP awards, the progress report is submitted using this streamlined version of the RPPR that does not include detailed budget information.

8.4.1.2.2 Modified NoAs

Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and any negotiations, and reduces the information NIH requires to review, approve, and monitor non-competing continuation awards. SNAP NoAs are issued with only total direct and F&A costs awarded for the budget period. While direct costs categorical breakdowns are not awarded, recipients are required to allocate and account for costs by category in accordance with applicable cost principles. Future year commitments on SNAP awards reflect total cost commitments (direct plus F&A costs).

8.4.1.2.3 Modified Financial Reporting Requirements

For awards under SNAP, an FFR is required only at the end of a competitive segment rather than annually. The FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout).

8.4.1.2.4 Submitting SNAP Progress Reports

All SNAP progress reports are due the 15th of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/15). If the 15th falls on a weekend or Federal holiday, the due date is automatically extended to the next business day. Paper submissions are not acceptable, will not be used for consideration for funding, and will not become part of the official file. If a paper SNAP progress report is submitted, recipients will be required to resubmit the information electronically.

The RPPR module in the eRA Commons allows recipients to electronically prepare and submit progress reports and supporting documentation. The RPPR module provides the user with dedicated screens to collect the required progress report information, including appropriate uploads for text documents. Data submitted through RPPR for Performance Sites and Participants is retained in the system to assist the recipient in completion of future progress reports.

The RPPR may be routed to authorizing officials at the applicant institution for review and approval prior to submission to NIH. For SNAP awards, the RPPR module provides recipients with the option to delegate to the PD/PI the authority to submit the progress report directly to NIH. This optional authority is managed on a PD/PI basis in the eRA Commons; such authority can be rescinded at any time.

Guidance on RPPR submission is documented in the RPPR Instruction Guide.

8.4.1.3 Progress Reports for Multiyear Funded Awards

A limited number of NIH grant awards are multi-year funded, i.e., not funded in budget years but funded in full at the start of the project period from a single fiscal year appropriation. The project period and the budget period are the same in a multi-year funded (MYF) award and are longer than one year. Progress reports for MYF awards are due annually on or before the anniversary of the budget/project period start date of the award. A progress report is not required if the award is in a no-cost extension period unless specifically required by the IC. The reporting period for a MYF progress report is the calendar year preceding the anniversary date of the award. For example, if an award is made on 04/01/2021, the MYF progress report is due on or before 04/01/2022, and should report on the activities performed under the award between 04/01/2021 and 03/31/2022. For the subsequent year the MYF progress report will be due 04/01/2023, and should report on the activities performed under the award between 04/01/2022 and 03/31/2023. Information on the content of a MYF progress report and instructions on how to submit the report through the eRA Commons are posted at http://grants.nih.gov/grants/policy/myf.htm and http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. The multi-year research performance progress report (MYRPPR) link to upload the report will be available two months before the anniversary date of the award, on the eRA Commons Status search page in the folder "List of Applications/Grants" in the "Action" column. Progress reports for MYF awards must be completed by the PD/PI, and then submitted by a Signing Official (SO) or a PD/PI with delegated authority from the SO to submit a progress report. Information about SO delegation of authority to a PD/PI to submit a progress report appears in the eSNAP User Guide under Section 2. Delegating Authority.

8.4.1.4 Final Research Performance Progress Report (F-RPPR)

The F-RPPR has replaced the Final Progress Report for closeout. NIH is no longer accepting Final Progress Reports. Generally, the F-RPPR format is the same as the current annual RPPR. As part of the F-RPPR recipients will be required to report on Project Outcomes. This section will be made publicly available, allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).

NIH will not maintain its previous Type 2 policy which stated that "whether funded or not" the progress report contained in the Type 2 application may serve in lieu of a separate final progress report. NIH now requires that organizations submit an Interim-RPPR while their Type 2 is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's F-RPPR.

See the F-RPPR Instructions for more information. Recipients should also review the information found in Final Research Performance Progress Report.

8.4.1.5 Financial Reports

Beginning April 1, 2022, recipients are no longer required to submit quarterly cash transaction reports 30 days after the end of each calendar quarter. Instead, PMS will pre-populate the cash transaction section (lines 10a through 10c) of the FFR using recipient real-time cash expenses information from PMS, and adjust recipient-reported disbursements to equal cash advance drawdowns on all non-closed sub-accounts (PMS type P). Recipients will be required to certify at the time of each drawdown whether the cash drawdown request is for reimbursement of actual expenditures or is an advance for immediate disbursement; recipients must assert that award funds are used in compliance with all award conditions and federal statutory requirements.

8.4.1.5.1 Cash Transaction Reports

The FFR has a dedicated section to document Federal cash receipts and disbursements. For domestic recipients this information is pre-populated by PMS using toolrecipient real-time cash expenses information from PMS, and adjust recipient-reported disbursements to equal cash advance drawdowns on all non-closed sub-accounts (PMS type P).

For awards issued to foreign organizations, even though payment is now through PMS, the requirement for quarterly cash reporting does not apply. These awards are now administered in PMS using sub-accounts and payments will be specific to each grant at the time the recipient draws funds. (See also Grants to Foreign Organizations – Administrative Requirements – Reporting and Record Retention.)

8.4.1.5.2 Financial Expenditure Reports

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the recipient organization. NIH requires all financial expenditure reports to be submitted using the Payment Management System. This includes all initial FFRs being prepared for submission and any revised FFRs being submitted or re-submitted to NIH. The eRA Commons and Payment Management systems allows participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH through PMS. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted by OFM. NIH IC grants management staff also review these expenditure reports.

Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date.

In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout).

Before submitting FFRs to NIH, recipients must ensure that the information submitted is accurate, complete, and consistent with the recipient's accounting system. When submitting the FFR through the eRA Commons, or Payment Management System, as applicable, the AOR or the individual designated to submit this report on behalf of their institution, certifies that the information in the FFR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal government. Filing a false claim may result in the imposition of civil or criminal penalties.

8.4.1.5.3 Revised Financial Reports and Expenditures

Revisions for F&A Changes. Each Federal Financial Report submitted by the recipient shall reflect the proper amount of F&A costs applicable to the grant period. If a provisional or an earlier period's permanent rate is used in the report, a subsequent adjustment to the FFR is necessary if a lower permanent

rate(s) applicable to the grant is established, except for Institutions of Higher Education (IHEs) subject to 2 CFR 200.

Revised Expenditure Reports. NIH requires all financial expenditure reports (domestic and foreign) to be submitted using the Payment Management System. This includes the initial FFR and any FFR revisions being submitted or re-submitted to NIH. In some cases the recipient may have to revise or amend a previously submitted FFR. When the revision results in a balance due to NIH, the recipient must submit a revised report whenever the overcharge is discovered, no matter how long the lapse of time since the original due date of the report. Revised expenditure reports representing additional expenditures by the recipient that were not reported to NIH within the 90-day time frame may be submitted electronically with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the recipient to preclude similar situations in the future. This should be done as promptly as possible, but no later than one year from the due date of the original report for annual FFRs and no later than 60 calendar days from the due date of the original report for final FFRs (i.e., 180 days from the project end date). If an adjustment is to be made, the NIH awarding IC will advise the recipient of actions it will take to reflect the adjustment.

8.4.1.5.4 Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. (See Administrative Requirements—Changes in Project and Budget for NIH approval authorities for unobligated balances.) Using the principle of "first in-first out," unobligated funds carried over are expected to be used before newly awarded funds.

Upon receipt of the annual FFR for awards other than those with authority for the automatic carryover of unobligated balances, the GMO will compare the total of any unobligated balance shown and the funds awarded for the current budget period with the NIH share of the approved budget for the current budget period. If the funds available exceed the NIH share of the approved budget for the current budget period, the GMO may select one of the following options:

- In response to a written request from the recipient, revise the current NoA to authorize the recipient to spend the excess funds for additional approved purposes.
- Offset the current award or a subsequent award by an amount representing some or all of the excess.

8.4.1.5.5 Recipient Reporting of Subrecipient Data and Executive Compensation Information for Federal Funding Accountability and Transparency Act (FFATA)

A component of Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires most recipients of new Federal funds to report on sub-awards/subcontracts/consortiums equal to or greater than $30,000. This includes awards that are initially below $30,000 but subsequent grant modifications result in an award equal to or greater than $30,000.

The FFATA Subaward Reporting System (FSRS) tool can be accessed directly at www.fsrs.gov, and will serve as the collection tool for subaward data which will ultimately be distributed for publication and display on www.USASpending.gov. Recipients are required to register with FSRS, collect the necessary data from subrecipients, and file subaward reports by the end of the month following the month in which the prime recipient awards any subaward greater than $30,000.

FFATA specifies the data that should be captured for each prime recipient and first-tier subrecipient of Federal awards, regardless of award type. To promote data consistency and reduce reporting burdens, existing agency data sources will be leveraged to pre-populate reports for prime recipients as well as for

subrecipients when available. Recipients are responsible for confirming the pre-populated data and providing any additional required information.

Included in these requirements is the need to report the names and total compensation of the five most highly compensated officers of the entity if the entity as part of their registration profile in SAM in the preceding fiscal year: 1) received 80 percent or more of its annual gross revenues in Federal grants, subawards, contracts, and subcontracts; and 2) received $25,000,000 or more in annual gross revenues from Federal grants, subawards, contracts, and subcontracts; and 3) had gross income, from all sources, of $300,000 or more; and 4) the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1). Additionally, recipient organizations may be required to verify the following information in FSRS:

- Organization UEI
- Name and Address of organization
- Parent UEI
- Assistance listing number
- FAIN
- Federal Awarding Agency of the grant

8.4.1.6 Invention Reporting

A complete list of the reporting requirements under the Bayh-Dole Act can be found at 37 CFR 401.14. The requirements also are specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

In addition to complying with Bayh-Dole-related regulations, each NIH competing grant application and non-competing continuation progress report must indicate whether or not any subject inventions were made during the preceding budget period. If inventions were made, the recipient must also indicate whether they were reported.

The recipient also must submit an annual invention utilization report for all subject inventions to which title has been elected and inventions that have been licensed but not patented (research tools). The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

A recipient's failure to comply with invention reporting requirements and/or associated NIH policies on intellectual property and resource sharing may result in the loss of patent rights or a withholding of grant funds or other enforcement actions, including the imposition of specific terms and conditions.

Bayh-Dole regulations allow recipients to report inventions electronically (37 CFR 401.16). NIH requires electronic reporting through an Internet-based system, Interagency Edison. To meet the objectives of the Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107), recipients are required to submit invention reports to NIH using iEdison. The system supports confidential transmission of required information and provides a utility for generating reports and reminders of pending reporting deadlines. Further information about the system, including instructions for creating an account needed to submit reports electronically, are on the iEdison site. Recipients also may contact the Division of Extramural Inventions and Technology Resources Branch, OPERA, OER. See Part III for contact information.

8.4.1.7 Financial Conflict of Interest Reports

Information related to FCOI reporting requirements can be found within Public Policy Requirements -- Financial Conflict of Interest.

8.4.1.8 NIH Disclosure Requirements

As part of the application preparation and submission process, and annual progress report submission, all individuals designated in an application as senior/key personnel are required to certify and submit information to assist reviewers and NIH staff in making informed recommendations and funding decisions. These disclosures are provided in the following proposal sections:

• Biographical Sketch; (see 2.3.7.12);

• Other Support (see 2.5.1); and

• Financial Conflicts of Interest (see 4.1.10)

Details on the required disclosures can be found in the NIH Disclosure Table. It is vital that submission of such disclosure information be taken seriously. Failure to comply with terms and conditions related to disclosure requirements may cause NIH to take action(s) to remedy non-compliance, such as disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action. Further, violations that are potentially criminal will be referred to the NIH Office of Management Assessment for consultation with the HHS Office of Inspector General, the Department of Justice, or other law enforcement agencies, as appropriate.

8.4.2 Record Retention and Access

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. For awards under SNAP (other than those to Federal institutions), the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. Federal institutions must retain records for 3 years from the date of submission of the annual FFR to NIH. See 2 CFR Part 200.334 and 45 CFR Part 75.361 for exceptions or qualifications to the 3-year retention requirement exist (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period), the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Maintain the information for the retention period for other types of grant-related records, including F&A cost proposals and property records. See 2 CFR Part 200.334 and 45 CFR Part 75.361 and 2 CFR Part 200.337 and 45 CFR Part 75.364 for record retention and access requirements for contracts under grants.

These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

NIH, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the NIH award, to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-Federal entity's

personnel for the purpose of interview and discussion related to such documents. The rights of access in this section are not limited to the required retention period but lasts as long as the records are retained. Pass-through entities must not impose any other access requirements upon non-Federal entities.

8.4.3 Audit

An audit is a systematic review or appraisal made to determine whether internal accounting and other control systems provide reasonable assurance of the following:

- Financial operations are properly conducted.
- Financial reports are timely, fair, and accurately.
- The entity has complied with applicable laws, regulations, and other grant terms.
- Resources are managed and used economically and efficiently.
- Desired results and objectives are being achieved effectively.

NIH recipients (other than Federal institutions) are subject to audit requirements in 2 CFR Part 200 Subpart F and 45 CFR Part 75, Subpart F and in the NIHGPS (for types of organizations to which 2 CFR Part 200, Subpart F-Audit Requirements and 45 CFR Part 75, Subpart F do not directly apply). In general, 2 CFR Part 200, Subpart F- Audit Requirements and 45 CFR Part 75, Subpart F requires a State government, local government, or non-profit organization (including institutions of higher education) that expends $750,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts are required to have an annual audit by a public accountant or a Federal, State, or local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing standards (GAGAS). The audit requirements for foreign recipients and commercial recipients are addressed in the chapters of this NIHGPS that provide specific requirements for those types of recipients.

As specified in the NoA, all awards issued by NIH meet the definition of "Research and Development" at 2 CFR Part 200.1 and 45 CFR Part 75.2. As such, NIH grant awards are subject to the R&D cluster of program requirements in the compliance supplement. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Exhibit 10. Summary of Audit Requirements

Recipient Type	Source of Audit Requirement	Where to Submit Audit Reports
State & Local Governments	2 CFR 200.501 and 45 CFR Part 75.501	Federal Audit Clearinghouse (See contact information in Part III)
Colleges & Universities (IHEs)	2 CFR 200.501 and 45 CFR Part 75.501	Federal Audit Clearinghouse (See contact information in Part III)
Non-Profits	2 CFR 200.501 and 45 CFR Part 75.501	Federal Audit Clearinghouse (See contact information in Part III)

Recipient Type	Source of Audit Requirement	Where to Submit Audit Reports
Hospitals	2 CFR 200.501 and 45 CFR Part 75.501	Federal Audit Clearinghouse (See contact information in Part III)
For-Profits	2 CFR 200.501 and 45 CFR Part 75.501	Audit Resolution Division (See contact information in Part III)
Foreign	NIH Grants Policy Statement (same as For-Profits)	Audit Resolution Division (same as For-Profits, see contact information in Part III)

When a recipient procures audit services, the procurement must comply with the procurement standards of 2 CFR Part 200, as applicable, including obtaining competition and making positive efforts to use small businesses, minority-owned firms, and women's business enterprises. Recipients should ensure that comprehensive solicitations made available to interested firms include all audit requirements and specify the criteria to be used for selection of the firm. Recipients' written agreements with auditors must specify the rights and responsibilities of each party.

2 CFR Part 200, Subpart F-Audit Requirements explains in detail the scope, frequency, and other aspects of the audit. Some highlights of this regulation are as follows:

- Covered organizations expending $750,000 or more per year in Federal awards are required to have an audit performed in accordance with the regulation. However, if the awards are under one program, the organization can have either a single organization-wide audit or a program-specific audit of the single program, subject to the provisions of 2 CFR Part 200.507. Prior to electing a program-specific audit, the recipient must obtain written prior approval from the NIH awarding IC. Covered organizations expending less than $750,000 in any year are exempt from these audit requirements in that year but must have their records available for review as required by Administrative Requirements—Monitoring—Record Retention and Access.
- The reporting package must contain the following:
    - Financial statements and schedule of expenditures of Federal awards.
    - Independent auditor's report, including an opinion on the financial statements and the schedule of expenditures of Federal awards, a report on compliance and internal control over financial reporting, and a report on compliance with requirements applicable to each major program and on internal control over such compliance requirements.
    - A schedule of findings and questioned costs.
    - If applicable, a summary of prior audit findings and a corrective action plan.
- An audit under 2 CFR Part 200, Subpart F-Audit Requirements is in lieu of a financial audit of individual Federal awards. However, Federal agencies may request additional audits necessary to carry out their responsibilities under Federal law or regulation. Any additional audits will build upon work performed by the independent auditor.
- The data collection form (SF-SAC) and a copy of the Single Audit reporting package must be submitted electronically to the FAC at the address provided in Part III.

- A senior level representative of the auditee (e.g., state controller, director of finance, chief executive officer, or chief financial officer) must sign a statement to be included as part of the data collection that says that the auditee complied with the requirements of this part, the data were prepared in accordance with this part (and the instructions accompanying the form), the reporting package does not include protected personally identifiable information, the information included in its entirety is accurate and complete, and that the FAC is authorized to make the reporting package and the form publicly available on a web site. Exception: An auditee that is an Indian tribe or a tribal organization (as defined in the Indian Self- Determination, Education and Assistance Act (ISDEAA), 25 U.S.C. 450b(l)) may opt not to authorize the FAC to make the reporting package publicly available on a web site, by excluding the authorization for the FAC publication. If this option is exercised, the auditee becomes responsible for submitting the reporting package directly to any pass-through entities through which it has received a Federal award and to pass-through entities for which the summary schedule of prior audit findings reported the status of any findings related to Federal awards that the pass-through entity provided. Unless restricted by Federal statute or regulation, if the auditee opts not to authorize publication, it must make copies of the reporting package available for public inspection.

If the schedule of findings and questioned costs discloses an audit finding related to an HHS or NIH award or if the schedule of prior audit findings reports the status of any audit finding relating to an HHS or NIH award, the FAC will provide copies of the audit report to NEARC, OIG, HHS. NEARC will, in turn, distribute them within HHS for further action, as necessary. Audit reports should not be sent directly to the GMO. The threshold for reporting questioned costs is described in 2 CFR Part 200.516 and 45 CFR Part 75.516.

Recipients must follow a systematic method for ensuring timely and appropriate resolution of audit findings and recommendations, whether discovered as a result of a Federal audit or a recipient-initiated audit. Recipients usually are allowed 30 days from the date of request to respond to the responsible audit resolution official (Action Official) concerning audit findings. Failure to submit timely responses may result in cost disallowance or other actions by NIH or HHS. At the completion of the audit resolution process, the recipient will be notified of the Action Official's final decision. The recipient may appeal this decision if the adverse determination is of a type covered by NIH or HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures). Refunds owed to the Federal government as a result of audit disallowances must be made in accordance with instructions issued by the Action Official or OFM.

It is imperative that recipients submit required 2 CFR Part 200, Subpart F and 45 CFR Part 75, Subpart F audits within the time limits specified in the regulation. If recipients are delinquent in complying with the provisions of the regulation, NIH will take one or more actions that may result in the loss of Federal funds. No audit costs will be allowed either as F&A costs or direct costs to Federal awards if the required audits have not been completed or have not been conducted in accordance with the provisions of 2 CFR Part 200, Subpart F.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of audit costs.

8.5 SPECIFIC AWARD CONDITIONS AND REMEDIES FOR NONCOMPLIANCE (SPECIFIC AWARD CONDITIONS AND ENFORCEMENT ACTIONS)

A recipient's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration

of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the recipient an opportunity to correct the deficiencies before taking action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing specific conditions on awards or precluding the recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

8.5.1 Specific Award Conditions: Modification of the Terms of Award

During grant performance, the GMO may include specific award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting NIH's interests and effecting positive change in a recipient's performance or compliance. When specific conditions are imposed, the GMO will notify the recipient in writing of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. See 42 CFR Part 52.9 and 2 CFR Part 200.339 and 45 CFR Part 75.371.

The NIH awarding IC may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform the research objectives. In that case, the awarding IC may request that the recipient designate a new PD/PI or other named senior/key personnel.

Generally, the decision to modify the terms of an award (e.g., by imposing specific award conditions) is discretionary on the part of the NIH awarding IC and is not appealable.

8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

If a recipient has failed to comply with the terms and conditions of award, NIH may take one or more enforcement actions which include disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action. NIH may also terminate the grant in whole or in part as outlined in 2 CFR Part 200.340 and 45 CFR Part 75.372. The regulatory procedures that pertain to suspension and termination are specified in 2 CFR Parts 200.340 through 200.343 and 45 CFR Part 75.372.

a. NIH or the pass-through entity must provide the non-Federal entity a notice of termination
b. If the award is terminated for the non-Federal entity's material failure to comply with the Federal statutes, regulations, or terms and conditions of the Federal award, the notification must state that:
    1. The termination decision will be reported to the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS);
    2. The information will be available in the OMB-designated integrity and performance system for a period of five years from the date of the termination, then archived;
    3. Awarding agencies that consider making a Federal award to the non-Federal entity during that five year period must consider that information in judging whether the non-Federal entity is qualified to receive the Federal award, when the Federal share of the Federal award is expected to exceed the simplified acquisition threshold over the period of performance;
    4. The non-Federal entity may comment on any information the OMB-designated integrity and performance system contains about the non-Federal entity for future consideration by HHS awarding agencies. The non-Federal entity may submit comments to the recipient integrity and performance portal accessible through CPARS.
    5. Federal awarding agencies will consider the non-Federal entity comments when determining whether the non-Federal entity is qualified for a future Federal award.
c. Upon termination of an award, NIH must provide the information required under FFATA to the Federal web site established to fulfill the requirements of FFATA and update or notify any other relevant government-wide systems or entities of any indications of poor performance as required by 41 U.S.C. 417b and 31 U.S.C. 3321. See also the requirements for Suspension and Debarment at 2 CFR Part 180.

NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. However, NIH may decide to terminate the grant if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate a grant when necessary, such as to protect the public health and welfare from the effects of a serious deficiency. Termination may be appealed under NIH and HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures).

A grant also may be terminated, partially or totally, by the recipient or by NIH with the consent of the recipient. If the recipient decides to terminate a portion of a grant, NIH may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, NIH will advise the recipient of the possibility of termination of the entire grant and allow the recipient to withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire grant.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of termination costs. Allowability of these costs does not vary whether a grant is terminated by NIH, terminated at the request of the recipient, or terminated by mutual agreement.

Withholding of support is a decision not to make a non-competing continuation award within the current competitive segment. Support may be withheld for one or more of the following reasons:

- Adequate Federal funds are not available to support the project.
- A recipient failed to show satisfactory progress in achieving the objectives of the project.
- A recipient failed to meet the terms and conditions of a previous award.

- For whatever reason, continued funding would not be in the best interests of the Federal government.

The recipient may appeal NIH's determination to deny (withhold) a non-competing continuation award because the recipient failed to comply with the terms and conditions of a previous award.

8.5.3 Other Enforcement Actions

Depending on the nature of the deficiency, NIH may use other means of promoting recipient compliance. Other options available to NIH include, but are not limited to conversion from an advance payment method to a reimbursement method or disallow (deny) all or part of the cost of the activity or action not in compliance. Other actions may include suspension or debarment of an organization or individual under Government-wide Debarment and Suspension rules provided at 45 CFR Part 76, and other available legal remedies, such as civil action. Suspension under 45 CFR Part 76, implementing E.O.s 12549 and 12689, "Debarment and Suspension," is a separate action from the "suspension" of an award as a post-award remedy, as described in Suspension, Termination, and Withholding of Support above. The subject of debarment and suspension as an eligibility criterion is addressed in Completing the Pre-Award Process—Determining Eligibility of Individuals and Public Policy Requirements and Objectives—Debarment and Suspension.

8.5.4 Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of a grant. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances. NIH guidance on the repayment of grant funds that are unrelated to audit findings can be found on the OER Web site.

8.5.5 Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for HHS in 45 CFR 30. NIH is required to collect debts due to the Federal government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

When NIH determines the existence of a debt under a grant, written debt notification will be provided to the recipient. Unless otherwise specified in law, regulation, or the terms and conditions of the award, debts are considered delinquent if they are not paid within 30 days from the date the debt notification is mailed to the recipient. Delinquent debts are subject to the assessment of interest, administrative cost charges, and penalties. The interest on delinquent debts accrues on the amount due beginning on the date the debt notification is mailed to the recipient.

If a recipient appeals an adverse monetary determination under 42 CFR Part 50, Subpart D, or 45 CFR Part 16, interest will accrue but assessment will be deferred pending a final decision on the appeal. If the appeal is not successful, interest will be charged beginning with the date the debt notification was mailed to the recipient, not the date of the appeal decision. Interest charges will be computed using the prevailing rate in effect on the date the debt notification is mailed, as specified by the Department of the Treasury and 45 CFR Part 30.13(a)(2).

8.6 CLOSEOUT

The requirement for timely closeout is generally a recipient responsibility. However, NIH may initiate unilateral closeout if a recipient does not provide timely accurate closeout reports or does not respond timely to NIH requests to reconcile discrepancies in grant records. If a recipient does not submit all required closeout reports within a year of the period of performance end date, NIH must report the recipient's failure to comply with the terms and conditions of award in FAPIIS and initiate unilateral closeout. Failure to submit timely and accurate closeout documents may affect future funding to the organization. Failure to correct recurring reporting problems may cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding or further awards, suspension or termination. NIH will close out a grant as soon as possible after the end date of the period of performance (no later than one year after the period of performance end date in accordance with 2 CFR Part 200.344) if the grant will not be extended or after termination as provided in 2 CFR Part 200.339 through 200.343 and 45 CFR Part 75.371. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due the recipient or NIH. Closeout of a grant does not automatically cancel any requirements for property accountability, record retention, or financial accountability. Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of the grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. (See 8.4.2 Record Retention and Access, for further information). Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the Federal government may recover amounts based on the results of an audit covering any part of the period of grant support.

Recipients must submit a final FFR, Final RPPR, and Final Invention Statement and Certification within 120 calendar days of the end of the period of performance (project period). The reports become overdue the day after the 120 calendar day period ends.

A subrecipient must submit to the recipient, no later than 90 calendar days (or an earlier date as agreed upon by the recipient and subrecipient) after the end date of the period of performance, all reports as required by the terms and conditions of award.

8.6.1 Final Federal Financial Report

A final FFR is required for

- any grant that is terminated,
- any grant that is transferred to a new recipient, or
- any award, including awards under SNAP, which will not be extended through award of a new competitive segment.

Recipients are required to electronically submit the final FFR through the Payment Management System. The final FFR must cover the entire competitive segment or as much of the competitive segment as has been funded before termination. Final FFRs must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the Federal share of expenditures reported on the final FFR and the net cash disbursements reported in PMS on the Transactions section of the FFR. Unobligated funds must be returned to NIH or must be reflected by an appropriate accounting adjustment in accordance with instructions from the GMO or from the payment office. It is the recipient's responsibility to reconcile reports **prior** to submission to PMS and to the NIH awarding IC. Withdrawal of the unobligated balance following completion date or termination of a grant is not

considered an adverse action and is not subject to appeal (see Administrative Requirements—Enforcement Actions—Recovery of Funds).

When the submission of a revised final FFR results in additional claims by the recipient, NIH will consider the approval of such claims subject to the following minimum criteria:

- The recipient must indicate why the revision is necessary and explain and implement internal controls that will preclude similar occurrences in the future.
- The charge must represent otherwise allowable costs under the provisions of the grant.
- There must be an unobligated balance for the budget period sufficient to cover the claim.
- The funds must still be available for use.
- NIH must receive the revised final FFR within one year of its original due date.

8.6.2 Final Research Performance Progress Report

A Final RPPR required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. If a competitive renewal (Type 2) application has been submitted, the recipient must submit an Interim-RPPR while their renewal application is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim RPPR will be treated by NIH staff as the institution's Final RPPR.

A Final RPPR should be prepared in accordance with the requirements in the RPPR Instructions found on the NIH RPPR web site and any specific requirements set forth in the terms and conditions of the award. In addition to the standard requirements detailed in those Instructions, recipients should also report additional information required by the awarding IC in program-specific final progress report instructions.

Final RPPR Instructions for SBIR/STTR Phase II Reports are in Section 7.3. of the RPPR Instructions.

8.6.3 Final Invention Statement and Certification

The recipient must submit a Final Invention Statement and Certification (HHS 568), whether or not the funded project results in any subject inventions, and whether or not inventions were previously reported. The HHS 568 must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, and it must be signed by an AOR. The completed form should cover the period from the original effective date of support through the completion date or termination of the award, and it should be submitted to the NIH awarding IC. If there were no inventions, the form must indicate "None." For certain programs (activity codes = C06, , D42, D43, D71, DP7, G07, G08, G11, G13, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UH4, UC6, UC7, UG4, UR2, X01, X02, Ts, and Fs), the Final Invention Statement and Certification is not currently required. For questions, the recipient should contact NIH awarding IC for specific instructions.

When invention reporting is required, the HHS 568 does not relieve the responsible party of the obligation to assure that all inventions are promptly and fully reported directly to NIH, as required by terms of the award. Copies of the HHS 568 form are available on the iEdison web site at http://iEdison.gov and at http://grants.nih.gov/grants/forms.htm.

8.6.4 Submission of Closeout Documents

All closeout documents must be submitted electronically via eRA Commons. NIH no longer accepts paper or e-mail submissions.

8.7 GRANT APPEALS PROCEDURES

HHS permits recipients to appeal certain post-award adverse administrative decisions made by HHS officials (see 45 CFR Part 16 and appendix to Part 16). NIH has established a first-level grant appeal procedure that must be exhausted before an appeal may be filed by the recipient with the Departmental Appeals Board (DAB) (see 42 CFR Part 50, Subpart D). NIH will assume jurisdiction for the following adverse determinations set forth in 42 CFR Part 50.404:

- Termination, in whole or in part, of a grant for failure of the recipient to carry out its approved project in accordance with the applicable law and the terms and conditions of award or for failure of the recipient otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
- Determination that an expenditure is not allowable under the grant has been charged to the grant or that the recipient has otherwise failed to discharge its obligation to account for grant funds.
- Denial (withholding) of a non-competing continuation award for failure to comply with the terms of a previous award.
- Determination that a grant is void (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

The formal notification of an adverse determination will contain a statement of the recipient's appeal rights. In the first level appeal of an adverse determination, the recipient must submit a request for review to the NIH official specified in the notification, detailing the nature of the disagreement with the adverse determination and providing supporting documents in accordance with the procedures contained in the notification.

"The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of the recipient's position with respect to such issue(s) and the pertinent facts and reasons in support of the recipient's position. In addition to the required written statement, the recipient shall provide copies of any documents supporting its claim." 42 CFR Part 50.406(b).

The recipient's request to NIH for review must be submitted no later than 30 days after the written notification of the adverse determination is received; however, an extension may be granted if the recipient can show good cause why an extension is warranted (42 CFR Part 50.406(a)).

If the NIH decision on the appeal is adverse to the recipient or if a recipient's request for review is rejected on jurisdictional grounds, the recipient then has the option of submitting a request to the DAB for a further review of the case in accordance with the provisions of 45 CFR Part 16. A prospective appellant must submit a notice of appeal to the DAB within 30 days after receiving the final NIH decision. "The appellant must have exhausted any preliminary appeal process required by regulation." 45 CFR Part 16.3 (c).

In addition to the adverse determinations indicated above, the DAB is the single level of appeal for disputes related to the establishment of F&A cost rates, research patient care rates, and certain other cost allocations used in determining amounts to be reimbursed under NIH grants (e.g., cost allocation plans negotiated with State or local governments and computer, fringe benefit, and other special rates. The determination leading to such disputes may be made by an HHS official other than the GMO and may affect NIH grants as well as other HHS grants.

PART II: TERMS AND CONDITIONS OF NIH GRANT AWARDS

Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities

This Subpart includes terms and conditions that vary from, are in addition to, elaborate on, or highlight the standard requirements and terms and conditions in IIA because of the type of grant, recipient, or grant-supported activity. Each chapter of IIB specifies how the coverage relates to that in IIA and must be used in conjunction with IIA to determine all of the applicable terms and conditions of a covered type of activity, recipient, or award.

This Subpart contains the following chapters:

- Multiple Program Director/Principal Investigator Applications and Awards
- Construction, Modernization, or Major Alteration and Renovation of Research Facilities (this chapter also includes requirements for specified A&R activities under non-construction grants)
- Individual Fellowships and Institutional Research Training Grants (also termed “fellowships” and “training grants”) under the Kirschstein-NRSA program
- Career Development Awards
- Modular Applications and Awards
- Support of Scientific Meetings (Conference Grants)
- Consortium Agreements
- Grants to Foreign Organizations, International Organizations, and Domestic Grants with a Foreign Component
- Grants to Federal Institutions and Payments to Federal Employees Under Grants
- Grants to Commercial Organizations
- Research Patient Care Costs.

9 MULTIPLE PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR APPLICATIONS AND AWARDS

9.1 GENERAL

Multiple Program Director/Principal Investigator (multiple PD/PI) awards are an opportunity for multidisciplinary efforts and collaboration through a team of scientists under a single grant award. All PD/PIs share equally the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the applicant organization, or as appropriate to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI. The applicant/recipient organization is responsible for securing and retaining the required written assurance signatures from each identified PD/PI on all applications, post-submission information, progress reports, and post-award prior approval requests and must make these signatures available to NIH or other authorized DHHS or Federal officials upon request.

NIH implementation of Multiple PD/PIs is in accordance with the January 4, 2005 Office of Science Technology Policy directive to Federal research agencies. Additional information on Agency implementation plans can be found at: http://rbm.nih.gov/toolkit.htm. NIH also maintains a Web site dedicated to the Multiple PD/PI initiative.

9.2 APPLICABILITY

Applications submitted electronically through Grants.gov for most award mechanisms permit multiple PD/PIs, with the exception of awards for which multiple PD/PIs would not be appropriate such as individual fellowship and career awards, dissertations grants (R36), Pioneer Awards (DP1), Construction Grants (C06/UC6), Grants for Repair, Renovation and Modernization of Existing Research Facilities (G20), and Shared Instrumentation Grants (S10). Applications submitted on the paper PHS 398 Grant Application may only include multiple PD/PIs if the option is clearly specified in the Funding Opportunity Announcement. SBIR/STTR applicants may use the multiple PD/PI option; refer to the SBIR/STTR multiple PD/PI section for specific requirements affecting small business concerns. For active awards, changing from a multiple PD/PI model to a single PD/PI model or changes in the number or makeup of the PD/PIs on a multiple PD/PI award requires the prior approval of the funding IC (see Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA).

9.3 APPLICATION REQUIREMENTS

The decision to submit a multiple PD/PI application is that of the applicant organization and the PD/PIs, and should be consistent with the scientific goals of the project. A single applicant organization may designate multiple PD/PIs from the applicant organization or may designate multiple PD/PIs from multiple institutions. Multiple organizations may not submit the same multiple PD/PI application.

All PD/PIs must be qualified and have appropriate expertise to serve as a PD/PI and the appropriate level of authority and responsibility to direct the project or program as part of the leadership team. Each PD/PI must have a defined role on the project. There is no limit on the number of PD/PIs that may be designated, and no minimum person months requirement, except STTR applicants where each PD/PI must commit a minimum of 1.2 calendar months (10%) effort (see Grants to For-Profit Organizations—SBIR and STTR Programs—Multiple PD/PI Applications and Awards).

Contact PD/PI. The applicant organization must designate one of the PD/PIs as the Contact PD/PI to serve as a primary point of contact. The Contact PD/PI must be listed first on the application and must be associated with the applicant organization. The Contact PD/PI is responsible for communication between the PD/PIs and NIH, but has no special authorities or responsibilities within the leadership team. Responsibilities of the Contact PD/PI may include communication between the leadership team and NIH, assembly of the application materials, and coordination of progress reports. On complex projects the Contact PD/PI may request additional effort for coordination responsibilities if necessary.

eRA Commons Registration Required. All PD/PIs must have established eRA Commons accounts with a PI role prior to application submission. When multiple PD/PIs are at different organizations, all organizations must also be registered in the eRA Commons. If the contact PD/PI is at a different institution from the applicant organization, then the applicant organization must also affiliate the contact PD/PI with their institution. Beyond the contact PD/PI, it is not necessary for all other PD/PIs to be affiliated with the applicant organization.

Leadership Plan. All multiple PD/PI applications are required to include a Leadership Plan. The purpose of the Leadership Plan is to facilitate and enhance scientific productivity and establish a decision-making process. The Plan must describe a rationale for choosing the multiple PD/PI approach. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs, including responsibilities for human subject studies or studies with vertebrate animals as appropriate.

New Investigators (Including Early Stage Investigators). Multiple PD/PI applications may designate senior and new investigators, including early stage investigators. However, the application will only be considered a new investigator application when all of the PD/PIs meet the NIH definition of new investigator, and will only be considered an early stage investigator application when all of the PD/PIs meet the NIH definition of early stage investigator. For the purposes of classification as a new investigator, serving as a PD/PI on a substantial independent PD/PI research award is equivalent to serving as a PD/PI on a substantial independent PD/PI research award. Thus, if a new investigator successfully competes as a PD/PI on a substantial independent multiple PD/PI grant, they no longer qualifies as a new (or early stage) investigator on a substantial independent single PD/PI application. However, if a new investigator is added as a PD/PI to an active substantial independent research award, the individual will retain their new investigator status.

Multi-Project Applications. Assuming the FOA for Multi-project applications (e.g., P01, P30) specifically allows multiple PD/PIs, applications may include multiple lead investigators for subprojects as well as multiple PD/PIs for the entire program. Do not confuse lead investigator(s) of a subproject or component of a multi-project application with multiple PD/PIs of the entire program. Lead investigator (s) of subprojects or components are not automatically considered to be PD/PIs of the entire application. When a lead investigator of a subproject or component is also a PD/PI of the entire program, that individual must specifically be designated as a PD/PI of the application.

Budgets. In general, multiple PD/PI applications will submit a single budget for the entire project. This applies to both modular and detailed budgets. When determining if a modular budget should be submitted, the $250,000 threshold is for the entire project, not per PD/PI. When multiple PD/PIs are at different institutions, the standard instructions for submitting consortium budgets apply. Applicants can choose to include budget allocation information for specific PD/PIs as part of the Leadership Plan. In the event of an award, the requested allocations may be reflected in a term in the NoA (see Leadership Plan above).

Renewal or Resubmission Applications. A renewal or resubmission application may change from a single PD/PI to multiple PD/PIs or may change the number or makeup of the multiple PD/PIs. However, the applicant must provide a rationale for the change in the renewal / resubmission application, and include the required Leadership Plan. Likewise, a previously submitted multiple PD/PI application may change to a single PD/PI application in a renewal or resubmission; the applicant must provide a rationale for the change in the application.

Competing Revision Applications. A competing revision application to an existing Multiple PD/PI grant must be submitted using the same Contact PD/PI as the parent grant, and may propose changes in the Leadership Plan or in the composition of the leadership (by adding or removing PD/PIs), and should provide a rationale for any such changes. A competitive revision to a single PD/PI grant may be submitted proposing multiple PD/PIs provided a Leadership Plan is also included.

9.4 APPLICATION REVIEW AND AWARD

The review criteria applied to multiple PD/PI applications are the same criteria applied to single PD/PI applications and each application will be evaluated on its own merit (see The Peer Review Process in Part I). Peer reviewers will consider each PD/PI's qualifications and identified role in the project. The leadership approach will be used to facilitate understanding of the complexities of the science and the management of the project. The quality of the Leadership Plan will be considered as part of the assessment of the overall approach and incorporated into the scientific and technical merit determination. Peer reviewers will not recommend that individual PD/PIs be removed; however, reviewers may recommend deletion of the specific aims and budget of a PD/PI, which would effectively remove the PD/PI's effort. The SRG must evaluate the application in its entirety without dropping components.

All PD/PIs are listed on the Summary Statement, in the NoA, and in NIH databases.

9.5 POST-AWARD ADMINISTRATION

If multiple PD/PIs are from multiple organizations, NIH will issue the award to the applicant organization which will administer the award using consortium or subaward arrangements in accord with the Consortium Agreements chapter. Budgets, including F&A costs associated with subawards, will be determined according to existing policy. Changes in the allocation and the size of subawards will be handled in the same way as single PD/PI awards.

Responsibility for all required reports is shared by the PD/PIs and the recipient institution. Only one of each required report should be submitted. Although all PD/PIs are responsible for the content of all reports, only one PD/PI should upload information in the eRA Commons. As with most other Commons features, only the recipient Signing Official may submit the reports to NIH, including closeout reports (final invention statement, progress report and financial status report).

Requests for administrative supplements must be submitted from an authorized official at the recipient organization and include the grant number and name of the Contact PD/PI in the request. For all applications, post-submission information, progress reports, and prior approval requests including requests to add or drop a PI, the recipient organization remains responsible for securing and retaining the required written assurance signatures from each identified PD/PI.

A change in Contact PD/PI may be designated in a non-competing continuation progress report; the Contact PD/PI must be a member of the existing leadership team and associated with the recipient organization. Revision of the Leadership Plan during the project period may be accomplished through a joint decision of the PD/PIs and reported in a non-competing continuation progress report.

All existing prior approval requirements apply to multiple PD/PI awards, including the change in status of any one of the PD/PIs or the addition of a PD/PI; refer to Administrative Requirements—Prior Approval Requirements in IIA. If a PD/PI withdraws from the grant or is no longer able to work on the project, a revised Leadership Plan or description of the impact on the project of a change to a single PD/PI award must be submitted as part of the prior approval request. NIH will evaluate the request considering the project as a whole, including the impact on the scope of work and budget.

If the Contact PD/PI changes institutions, the recipient institution will need to consider options. Since it is required that the Contact PD/PI be affiliated with the recipient institution in the Commons, the institution may choose to designate another PD/PI as the Contact. Another option would be to relinquish the grant and allow it to be transferred. Contact PD/PIs considering transferring should consult with the NIH awarding IC early in the process to discuss options.

10 CONSTRUCTION, MODERNIZATION, OR MAJOR ALTERATION AND RENOVATION OF RESEARCH FACILITIES

10.1 GENERAL

The chapter uses the following definitions:

- ***Construction.*** Construction of a new building, structure or facility, including the installation of fixed equipment, which provides space not presently available. It excludes the purchase of land and ancillary improvement, for example parking lots, roads, or fencing. The construction of shell space is not allowable as a construction activity since shell space does not provide usable space for research activities.
- ***Modernization.*** Alteration, renovation, remodeling, improvement, expansion or repair of, or completion of shell space in an existing building (whether for storage or human occupancy) necessary to make the building suitable for use for the purposes of a particular program. Modernization is distinct from construction in that it leaves the existing structure in place. This can range from updating flooring to replacing everything except for the existing mainframe and foundations. When the primary purpose of the award is to modernize biomedical research facilities, the grant cannot support the conduct of any research.

Alteration and Renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose of the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants.

To issue awards with the primary purpose of construction or modernization, an IC must have specific statutory authority allowing construction or modernization. Even if NIH has this authority, a recipient may not incur costs for any of these activities unless NIH specifically authorizes such costs.

NIH generally requests applications, and makes awards, for construction or modernization under grants or cooperative agreements specifically for that purpose. The recipient retains the primary responsibility for the project, including all phases of design and construction. When needed, under cooperative agreements, there is substantial scientific/programmatic staff involvement during the performance of the activity, which may include providing technical assistance in designing, constructing, and commissioning the facility and coordinating collaboration with other IC funded construction activities.

In addition, an applicant/recipient may propose to undertake an A&R project(s) under a grant whose primary purpose is other than construction or modernization. NIH characterizes these A&R projects as “minor” or “major,” depending on the type of activity proposed (see definitions above). If a post-award change would result in an A&R project that meets the definition of construction or Major A&R the recipient must notify the GMO in order for the IC to determine whether it is construction and whether the IC has the necessary statutory authority. The requirements that apply to minor A&R projects are addressed in IIA. Minor A&R projects are not required to satisfy all of the requirements of this chapter. Major A&R projects are subject to the requirements of this chapter as indicated.

Except where indicated, the requirements in this chapter apply to NIH grant-supported construction or modernization in lieu of the requirements in IIA. For major A&R projects, this chapter applies to the A&R activity only and IIA pertains to the other grant-supported activities under the same award, if any. However, there may be areas of overlap (e.g., a post-award change that causes a minor A&R project to become a major A&R project). See Exhibit 11 for a summary of the requirements specified in this chapter and their potential applicability to construction, modernization, or major A&R.

This chapter addresses all aspects of grant-supported construction, modernization, and major A&R from application through closeout. Due to the size and complexity of these activities, this chapter describes in detail requirements and recipient responsibilities related to procurement of construction services (see Procurement Requirements for Construction Services below). Applicants and recipients also should refer to the construction grant program regulations (42 CFR Part 52b), which, by their terms, apply to construction and modernization grants as well as major A&R under a research grant mechanism; 2 CFR Part 200; andapplicable administrative regulations; and program guidelines. Questions concerning construction or modernization grants or major A&R requirements or policies should be directed to the GMO or other official designated in the NoA.

10.1.1 Eligibility

In addition to any program-specific eligibility criteria, only public or private non-profit entities located in the United States or in U.S. territories or possessions are eligible to apply for construction or modernization grants. Commercial organizations and foreign organizations are not eligible to receive NIH construction or modernization grants. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants.

10.1.2 Funding Opportunity Announcements

Construction grant applicants are required to apply in response to a specific FOA. RFAs generally are used to solicit construction or modernization grant applications. PAs also may be issued to solicit construction or modernization grant applications for ongoing programs for which applications may be submitted under multiple cycles or years.

In addition to the FOA, NIH awarding ICs also may develop program guidelines that include detailed policy and procedural information applicable to specific construction and modernization grant programs/activities. Any program-specific requirements will be included in or referenced in the FOA and NoA. Applicants should consult the FOA and program guidelines, if any, when applying for construction or modernization grants.

10.1.3 Application Review and Award

Construction and modernization grant applications and applications requesting funding for a major A&R project are subject to peer review. Specific review criteria are included in the FOA.

Construction and modernization grants usually involve a single award, covering more than one year, made on the basis of an application for the entire project. Incremental funding (budget periods) within a project period normally is not used for construction or modernization grants and funding may be limited by the requirements of Federal appropriations law (31 U.S.C. §1552(a)) which may limit NIH's ability to approve no-cost extensions. Recipients must consult with the GMO if it is expected that the construction or modernization activity is unlikely to be concluded within the project period specified in the NoA.

Unlike other grants awarded by NIH, under which a recipient's signature is not required to indicate acceptance of an award, under construction and modernization grants, the AOR must sign the NoA and return it to the GMO to indicate acceptance of the terms and conditions of award.

10.1.4 Title to Site

NIH expects that the applicant holds (or will hold) fee simple title (i.e., absolute ownership of real property or absolute title to land, free of any claims against the title) to the property or other estate or interest in the site (e.g., leasehold interest) on which the construction, modernization, or major A&R is performed. NIH will determine whether an applicant meets this requirement as part of the administrative review of an application.

The applicant must include with the application a legal opinion describing the interest the applicant has in the performance site. The legal opinion should describe any mortgages or other foreclosable liens on the property, including the principal amount of the mortgage (and rate of interest); the dates of the mortgage; the terms and conditions of repayment; the appraised value of the property; and any provisions designed to protect the Federal interest in the property.

10.1.5 Matching Requirement

The requirements for recipients to share in the cost of the project are set forth in 42 CFR Part 52.b.6, *What is the rate of federal financial participation?* Unless otherwise specified by statute, the rate of federal financial participation in a construction project cannot be more than 50 percent of allowable construction costs. NIH can waive this requirement; however, it is not automatic and must be requested from the IC prior to application submission.

Matching may be in the form of allowable costs incurred by the recipient or a contractor under the grant. NIH generally does not allow recipients to use the value of third party in-kind contributions as a source to meet a matching requirement; however, the GMO may allow third party in-kind contributions included in the application budget on an exception basis. Third party in-kind contributions are the value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property and the value of goods and services directly benefiting and specifically identifiable to the project or program. To be allowable as matching, costs and in-kind contributions (if authorized) must meet allowability and documentation requirements of 2 CFR Part 200.306, as applicable. Costs and third party in-kind contributions claimed as matching also are subject to the requirements in IIA that apply to the expenditure of NIH funds.

The source and amount of funds proposed by an applicant to meet a matching requirement must be identified in the application. The applicant also will be required to demonstrate that the funds are committed or available at the time of, and for the duration of, the award. Exception to "cash on hand" will require negotiation with NIH prior to award. This may take the form of an assurance, as specified by the NIH awarding IC. The amount of NIH (Federal) funds awarded, combined with the non-Federal share, will constitute the total approved budget as shown in the NoA. The prior approval and other dollar thresholds contained in this chapter are based on the total approved budget unless otherwise specified. Downward adjustments to the matching requirement after award are a prior approval action. If NIH approval is not received in advance it is considered a violation of the terms and conditions of the construction award and may warrant enforcement action.

In addition to sharing in the costs of a construction grant, the recipient must ensure the availability of sufficient funds for operation (or continued operation) of the facility when construction or modernization is completed to allow the effective use of the facility for the grant-supported purposes.

10.2 PROCUREMENT REQUIREMENTS FOR CONSTRUCTION SERVICES

10.2.1 General

Construction, modernization, and major A&R activity usually is carried out through one or more contracts under the grant. Therefore, the circumstances of the procurement are critical to the successful completion of the grant-supported project. Recipient procurement must comply with the requirements specified in 2 CFR Parts 200.317 through 200.327 and 45 CFR Part 75.326, as applicable. Recipients must use only those contracting methods that will:

- Ensure that all qualified contractors are given an opportunity to bid or propose and to have their bids/proposals fairly considered.
- Ensure that the contract(s) will result in the completion of a facility—ready for occupancy—that conforms to the design and specifications approved by NIH (or any appropriate modification thereof also approved by NIH), at a cost that is within the owner's ability to pay.

Unless otherwise authorized by NIH, all work associated with NIH grant-supported construction, modernization, or major A&R must be procured by formal advertising, resulting in lump-sum, fixed-price contracts using the Design-Bid-Build model. NIH may authorize other procurement methods and other types of contracts when sealed bidding is impractical (see Construction-Alternate Contracting Methods). The recipient must obtain NIH approval of final construction documents both before bids or proposals are solicited and prior to the award of the contract. The recipient must ensure that the project is completed in accordance with the approved plans and specifications or secure NIH approval of any changes that materially alter the scope or costs of the project, use of space, or functional layout.

The two basic means of ensuring that a contract can be awarded at, or very near, the budgeted amount are accurate cost estimating and the use of bid alternates.

A precise description of the scope of work, specifications, materials, and construction techniques will facilitate accurate cost estimating by the recipient and, ultimately, the responsive bidders. The description of the scope of work is especially important when multiple contracts will be awarded in support of the same project, because each contractor must know exactly what is involved in the portions of the job being bid.

Where practical, the recipient may request in the invitation for bids, alternates to the base bid which are keyed to specified, and explicitly stated, changes in the project scope, materials, or construction techniques. The invitation may contain either additive alternates (adjustments increasing the amount of the base bid), or deductive alternates (adjustments reducing the amount of the base bid), or both. Additive alternates will make it possible to incorporate necessary features that otherwise would not have been included in the project as long as the features do not expand the scope of the peer reviewed and approved project. Alternates that are selected may be included in determining the low aggregate bid.

If, notwithstanding the use of deductive alternates, all bids exceed the funds available, the recipient may:

- Decline to award the contract(s) and instead, after NIH approval, issue a revised invitation for bids containing changes in the bid documents or other factors affecting price.
- Negotiate with the low bidder. All changes in design and specifications resulting from such negotiations must be approved by NIH. If the low bidder refuses to negotiate, negotiations may be entered into with the next lowest bidder. If efforts to negotiate are unsuccessful, all bids must be cancelled and the project rebid.

If the NIH-supported project is less than the entire facility or project, the recipient must obtain bids or proposals that provide the costs for that portion of the total job that will be paid by NIH funds and any required matching. This may be done in one of the following ways:

- If the project consists of more than one building or site and can be divided for purposes of obtaining a price or cost estimate and for carrying out the construction or modernization, showing the cost for each building or site, or
- If the project is a single site or contains common space and cannot be divided for pricing and construction or modernization purposes, identifying or prorating the applicable costs or price.

10.2.2 Liquidated Damages

Invitations for bids must stipulate a time for completion of the project, expressed either in calendar days or as a fixed date, for each prime contract to be awarded under the project.

At the option of the recipient, a liquidated damages provision may be included in the contract, allowing for assessment of damages when the contractor has not completed the construction by the date specified in the contract. Liquidated damages must be realistic and justified and must be approved by NIH before solicitation. Where damages are assessed, any amounts paid belong to the recipient.

10.3 CONTRACTING METHODS

10.3.1 Design-Bid-Build

The traditional three-phase project delivery method in which the recipient contracts with separate entities for each the design and construction phase of a project. It begins with a project design phase, followed by the construction bid phase (including solicitation and selection of a construction contractor), and then the active construction phase.

10.3.2 Alternate Contracting Methods

The use of a contracting method other than Design-Bid-Build, including the use of construction management services or design-build services as described below, may be authorized by NIH when cost, time, and quality benefits will result. In making such determinations, NIH will consider the scope of the project, estimated cost, and other factors deemed relevant. NIH approval must be received before the recipient begins the process of using an alternate contracting method.

If a construction management firm is currently employed, the recipient may choose to authorize that firm to perform the construction work. Such authorization requires NIH prior approval and the price for the work involved must not exceed the GMP also approved by NIH.

10.3.2.1 Construction Manager

10.3.2.1.1 Construction Manager as Agent

Use of construction management services, under which the recipient contracts for technical consultation during the design stage of a project and for organization and general project oversight of construction activities during the construction phase, is considered professional services and, therefore, may be procured on a negotiated basis rather than by formal advertising. However, the services of CMs may be procured by formal advertising in those cases where State or local governments prohibit the award of construction management contracts on a negotiated basis. Where bids are invited, the bidders should be pre-qualified. Under this procedure, the CM, operating as a member of a recipient-architect-CM team, is

responsible for cost estimates during the design and construction as well as cost control, review of design (s) with a view toward value engineering, consultation on construction techniques, construction coordination and scheduling, and oversight of all construction activities. The CM's fee is considered an eligible cost for the purpose of determining the total eligible cost of the project.

10.3.2.1.2 Construction Manager-at-Risk

A CM-at-Risk is considered a sole proprietorship, partnership, corporation, or other legal entity that assumes the financial risk for construction, rehabilitation, alteration, or repair of a facility at a GMP (see Construction-Alternate Contracting Methods-Guaranteed Maximum Price). The CM-at-Risk serves as a general contractor and provides consultation to the client during the design of the facility and through construction. The terms of the CM's employment must be such as to preclude any conflict of interest. The recipient may authorize the CM as Agent to become the CM-at-Risk to perform the construction services when authorized by NIH.

Under this procedure:

- The construction management contract must place total financial responsibility on the CM to complete construction of the project at or below a GMP. The CM is required to provide 100 percent performance and payment bonds to ensure that the facility can be completed with the amount of funds available.
- The GMP must be obtained from the CM before NIH will authorize the award of the first construction contract. This requirement applies whether or not phased construction techniques are employed. Each portion of the work for which a separate contract is expected shall be separately priced as an individual line item in the GMP contract.

10.3.2.2 Design-Build Services

Design-build is a method of project delivery in which one entity works under a single contract with the project owner to provide design and construction services. In design-build contracting, construction firms respond to a request for proposals by submitting building designs that meet the recipient's performance requirements within a GMP (see Construction-Alternate Contracting Methods-Guaranteed Maximum Price) covering all architectural, engineering, and construction services required. The design-build firm must be selected in a manner that will allow maximum feasible competition. Because of the nature of design-build contracting, the following departures from formal advertising are authorized:

- Cost will be treated as a competitive factor although the recipient may insert in the request for proposals a specified maximum permissible figure.
- A contract may be awarded regardless of the number of proposals received or the number of firms determined to have met qualification standards.
- The recipient may negotiate cost or design with one or any number of firms.

The selection of a design-build firm must be accomplished by a process that includes the following activities:

- Preparation of a RFP describing the recipient's design requirements, cost requirements, standards for qualifying firms, and the criteria on which proposals will be judged.
- Public announcement of the RFP.
- Consideration of all proposals from firms that are determined to be qualified.
- Selection of that firm that, in the recipient's judgment, represents the best offer considering both the firm's qualifications and satisfaction of the criteria in the RFP.

On all design-build projects, the recipient must:

- Ensure a firm total cost by including in the contract a provision that extra costs resulting from errors or omissions in the drawings or estimates will be the design-build firm's responsibility.
- Justify cost on the basis of comparability with similar construction.

10.3.2.3 Guaranteed Maximum Price

Under this procedure:

- The Guaranteed Maximum Price (GMP) contracting method can be used in either Construction Manager at Risk contracts or as part of Design-Build Services contracts. In either case, the project must be completed at or below the GMP.
- The recipient must transmit all GMP bids to the GMO, with its recommendation for award to the lowest responsive, responsible bidder.
- The GMP must be completely itemized, by trade, to include a separation of labor and materials, all markups, and no contingency other than that which will cover change orders as approved by the recipient.
- After approval of the GMP, all GMP subcontracts must be competed, and there must be at least three bidders to allow for an award.
    - Issue a "sources sought" announcement describing the nature of the construction work required, the separate contracts to be awarded, and the standards for prequalification. It must also describe the complete scope of work with sufficient specificity to ensure response from all interested sources.
    - Pre-qualify all firms that respond to the announcement who are determined by the recipient to meet the prequalification standards.
    - Establish bidder's lists for each of the invitations to bid. The lists must include all firms qualified on the basis of responses to the "sources sought" announcement and may also include other qualified firms known to the recipient.
    - By written invitation, solicit bids from all firms on the bidders list.
    - Consider bids from any contractor who requests permission to bid and who is determined by the recipient to meet the prequalification standards.
    - If three bids cannot be obtained, the recipient must submit, in writing, to the GMO a detailed explanation of why the GMP contractor is unable to comply, along with supporting documentation for NIH consideration and approval of another alternate contracting method.
    - Funds unexpended, due to lower construction costs than estimated in the GMP, must be refunded or credited to the recipient by the contractor and by the recipient to NIH. All costs in excess of the GMP are the responsibility of the GMP contractor.
    - All subcontract prices must be approved by the GMO before making individual awards. The awards shall be made to the lowest-priced responsible, responsive bidders.

10.4 DESIGN DOCUMENTATION REQUIREMENTS

Unless otherwise specified in the NoA, following award acceptance for construction or modernization grants or award of funds for a major A&R project, the recipient may begin the design phase of the award, which includes the review, and approval of the design documents with the IC program or other

designated NIH staff. Funds for construction, modernization, or major A&R will not be released until the final architectural drawings, specifications, construction schedule, and updated cost estimates are reviewed and approved by the NIH IC unless otherwise indicated in the NoA. The release of funds is accomplished by a revised NoA. The purpose of the NIH design review is to ensure that applicable design standards, including, as applicable, the minimum requirements contained in 42 CFR Part 52b.12 (see Minimum Requirements for Construction, Modernization, and Major A&R below), have been incorporated into the working drawings and specifications to ensure that program requirements are met, and that the facility will suitably accommodate the activities for which it is planned to be used.

Advertisement for bids may be initiated only after approval of the final construction documents by the NIH awarding IC. The procurement methods to be employed, including any plans that involve a construction management contract with a GMP clause, must be reviewed and approved by the NIH awarding IC.

10.4.1 Minimum Design Requirements for Construction, Modernization and Major A&R

The minimum design requirements for NIH grant-supported construction or modernization are set forth in 42 CFR Part 52b.12. The *NIH Design Requirements Manual* incorporates the regulatory standards for construction or modernization grants and those for major A&R projects.

Section 1.1.2 of the Design Requirements Manual provides the Required Codes and Standards for construction. The recipient will be subject to the standards in effect at the time of design or construction (modernization or A&R), as appropriate. Working drawings and specifications submitted for NIH approval (see Design Documentation Requirements above) must conform to the minimum standards in the NIH Design Requirements Manual. The NIH Design Requirements Manual also include policies, design standards, and technical criteria for use in planning, designing, and constructing or altering / renovating buildings owned or leased for use by NIH. Recipients are not subject to NIH site specific requirements contained in the NIH Design Requirements Manual but should meet the intended design objectives in such cases.

Recipients also must ensure that each project meets the requirements of the applicable State and local codes and ordinances. Where State or local codes are proposed as a basis for facility design in lieu of NIH design requirements, a prior determination must be made by the NIH awarding IC that the specific State or local code is equivalent to, or exceeds, NIH requirements. If State and local codes or requirements exceed the design requirements set forth in NIH regulations, the *NIH Design Requirements Manual* or program guidelines, the more stringent requirements will apply.

In planning and designing construction or modernization projects, recipients must consider that the facility is generally subject to an extended usage requirement, e.g., 10 or 20 years, after the date of occupancy and it should be constructed accordingly.

NIH will monitor compliance with design requirements during the project's design and construction phase. Recipients (or applicants) with questions concerning the applicability of requirements contained in the *NIH Design Requirements Manual* should consult with the NIH PO.

10.5 EQUAL OPPORTUNITY AND LABOR STANDARDS

Labor standards and equal employment opportunity requirements for federally assisted construction must be specified in the information provided to potential bidders/offerors on contracts for construction services under NIH construction and modernization grants and major A&R projects and must be included in the resulting contract documents (see 2 CFR Part 200, Appendix II to Part 200-Contract Provisions for

Non-Federal Entity Contracts Under Federal Awards). NIH construction and modernization grants and major A&R projects (and contracts under them) are not subject to the requirements of the Davis-Bacon Act, unless the authorizing statute for the program/award specifically requires compliance.

10.5.1 Equal Employment Opportunity

Contracts (and subcontracts) for construction (including modernization or major A&R) are subject to the requirements of EO 11246 (September 24, 1965), as amended and implemented in 41 CFR Part 60-1 by OFCCP, DoL. The recipient is required to include the "Equal Opportunity Clause" at 41 CFR Part 60-1.4 (b) in any contract for construction services under the grant. The contractor must be directed to include this clause in any applicable subcontracts.

In addition, recipients and contractors providing construction services under NIH grants are required to comply with the solicitation and contract requirements for affirmative action specified in 41 CFR Part 60-4 for contracts in specified geographical areas that will exceed $10,000. These requirements are specified in the "Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity" and the "Standard Federal Equal Employment Opportunity Construction Contract Specifications" subsections of 41 CFR Part 60-4.

The OFCCP regulations also require that the recipient notify the applicable OFCCP regional, area, or field office when it expects to award a contract for construction services that will exceed $10,000.

Further information about these requirements and the full text of these regulations are available at http://www.dol.gov/ofccp/.

10.5.2 Nonsegregated Facilities

Pursuant to 41 CFR Part 60-1.8, for any contract for construction services that will exceed $10,000, the recipient must require that each prospective contractor:

- Does not, and will not, maintain any facilities it provides for its employees in a manner that is segregated on the basis of race, color, religion, sex or national origin;
- Does not, and will not, permit its employees to perform their services at any location, under the contractor's control, where segregated facilities are maintained; and
- Will ensure that prospective subcontractors under any covered subcontract do not maintain segregated facilities or perform services at segregated facilities.

10.5.3 Labor Standards

10.5.3.1 Contract Work Hours and Safety Standards

Contractors and subcontractors providing construction services under NIH construction or modernization grants or major A&R projects with contracts or subcontracts exceeding $100,000 are subject to the requirements of the Contract Work Hours and Safety Standards Act, 40 U.S.C. 3701, et seq., concerning the payment of overtime and the maintenance of healthful and safe working conditions.

Wages paid any laborer or mechanic employed by the contractor or subcontractor must be computed on the basis of a standard workweek of 40 hours. For all work in excess of the standard workweek, mechanics and laborers shall be compensated at a rate not less than one-and-a-half times the basic rate of pay. If this requirement is violated, the contractor or subcontractor is liable to the employee for the unpaid wages and may be liable to the Federal government for liquidated damages. NIH or the recipient may

withhold otherwise payable funds to satisfy any such liability. The statute also specifies penalties for intentional violation of these requirements.

Further, pursuant to standards issued by the Secretary of Labor, no contractor or subcontractor under an NIH grant shall require any laborer or mechanic employed in the performance of the contract to work in surroundings or under working conditions that are unsanitary, hazardous, or dangerous to an individual's health or safety. Violation of these requirements may be cause for debarment from future Federal contracts or financial assistance.

10.5.3.2 Disposition of Unclaimed Wages

During or after the period of performance of a contract for construction services under an NIH grant, if it is discovered that an employee is entitled to wages but cannot be located for the purposes of payment (or for some reason refuses to accept payment), the recipient may eventually have to repay the Federal government. Therefore, NIH suggests that the contractor be required to turn over any unclaimed wages to the recipient.

The recipient should notify the GMO that an escrow account has been established in the affected employee's name and should maintain the account for 2 years (or longer if required by State or local law) following the completion of the contract. Upon the expiration of this period, any amounts still unclaimed will be disbursed by refunding to NIH either the entire amount, if the construction, modernization, or major A&R project was 100 percent funded by NIH, or an amount representing the percentage of NIH participation in the project. If the project was funded by more than one NIH or HHS program at differing rates, the refund should be based on an average percentage calculated by weighting each program's rate of participation by the dollar amount of that program's contribution.

If the contractor has made a reasonable effort to locate the employee by having mail forwarded and contacting the employee's union, the recipient need not repeat such attempts. If there is reason to believe that the contractor's efforts to locate employees that are due wages were not thorough, the recipient should attempt to locate the employees. Doing so will reduce the likelihood of future claims against the recipient.

If any wages held in escrow are paid to an employee or an employee's legal representative while the account is maintained, a complete report must be made to the GMO when the account is closed.

10.6 REAL PROPERTY MANAGEMENT STANDARDS

10.6.1 General

Unless alternate requirements are specified in the governing statute:

- Construction, modernization and major A&R under research grants are subject to the requirements of 42 CFR Part 52b.
- Major A&R under center grants or minor A&R under other types of grants/mechanisms is subject to the provisions of 2 CFR Part 200.310 through 200.316 and 45 CFR Part 75.307 through 45 CFR Part 75.323, as applicable, regarding use, transfer of title, and disposition.

Statutory provisions may specify alternate requirements for the length of the recipient's accountability obligations, the Federal right of recovery, or waivers. To the extent statutory provisions differ from the requirements of 42 CFR Part 52b and/or 2 CFR Part 200, including those described in this subsection, the statutory provisions, as reflected in the terms and conditions of the award, apply.

Real property constructed, modernized, or otherwise altered as part of a major alteration with NIH grant support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient, except as expressly authorized in writing by NIH. If the recipient defaults in any way on a mortgage, the recipient shall immediately notify the GMO by telephone and in writing. If the mortgagor intends to foreclose, the recipient must notify the GMO in writing at least 30 days before the foreclosure action is initiated.

The mortgage agreement must specifically allow, in the case of default, that NIH or its designee may assume the role of mortgagor and continue to make payments. If NIH (or its designee) chooses not to assume the role of mortgagor, the mortgagee (recipient) must pay NIH an amount equal to the share of the sales proceeds otherwise due the recipient (mortgagor) times the Federal share in the property.

Any NIH assignment of the property and mortgage responsibilities to any party other than NIH shall be subject to prior approval of the mortgagor.

10.6.2 Notice of Federal Interest

To protect the Federal interest in real property constructed, or where applicable, improved with NIH grant funds, recipients shall record a NFI in the appropriate official records of the jurisdiction in which the property is located as required by 2 CFR Part 200.316 and 45 CFR Part 75.323 and the NIHGPS. The NFI is required when use and disposition conditions apply to the property as stated in the NoA. The time of recordation shall be when construction begins. The recipient should consult with the GMO prior to recording the NFI, if necessary, to determine if the NFI is required under the award. Fees charged for recording the NFI may be charged to the grant (see Allowable and Unallowable Costs and Activities in this chapter). A copy of the recorded NFI must be provided to the GMO within 10 days following the date of recordation. To obtain a sample NFI, contact the GMO.

10.6.3 Insurance Requirements

Builder's risk insurance is required at the time construction begins. The insurance must cover potential losses after initiation, but before completion, of the construction or modernization caused by theft, fire, vandalism, and other types of accidental loss or damage to the structure.

Immediately upon completion of construction, a nongovernmental recipient shall, at a minimum, provide the same type of insurance coverage as it maintains for other property it owns, consistent with the minimum coverage specified below. "Completion of construction" means either the point at which the builder turns a facility constructed with NIH grant support, or portion of a facility modernized or modified under a major A&R project, (that conforms to the design and specifications approved by NIH and is available for occupancy) over to the recipient (i.e., the date of the final acceptance of the building or portion of a building) or the date of beneficial occupancy, whichever comes first.

If title to real property constructed, modernized, or altered under a major A&R project under an NIH grant vests (or will vest upon completion) in the recipient, the following minimum insurance coverage is required:

- Title insurance policy that insures the fee interest in the real property for an amount not less than the full appraised value of the property. When the Federal participation covers only a portion of a building, title insurance should cover the total cost of the facility to prevent liens on the unsecured portion from having an adverse impact on the portion with a Federal interest. In those instances where the recipient already owns the land, such as a building being constructed in the middle of a campus setting, in lieu of a title insurance policy, the recipient may provide evidence satisfactory to the NIH awarding IC, such as legal or title opinion, that it has good and merchantable title free of all mortgages or other foreclosable liens to all land, rights of way, and easements necessary for the project. In instances where a recipient is given land by the State, if the State recently acquired the land in a land swap transaction, the recipient should obtain title insurance. However, if the State has owned the land for a considerable period of time (i.e., 5 years or more), title insurance would not be necessary; a copy of the State documents giving the land to the recipient would be sufficient. If the recipient must buy the land on which to build, a legal opinion would not be sufficient; title insurance must be obtained in order to protect the Federal interest in the building to be constructed.
- Physical destruction insurance policy that insures the full appraised value of the facility (whether owned or leased by the recipient) from risk of partial and total physical destruction. When the Federal participation covers only a portion of a building, the insurance should cover the total cost of the facility, because any damage to the building could make the building unusable and could thus affect the Federal interest. The insurance policy is to be maintained for the duration of the Federal interest in the property (see Real Property Management Standards—Use of Facility and Disposition in this chapter). The cost of insurance coverage after the period of grant support must be borne by a source other than the grant that provided the funds for the grant-supported project. The grant account will not remain active for this purpose.

Governmental recipients may follow their own insurance requirements. Federally owned property provided to a recipient for use need not be insured by the recipient.

The NIH awarding IC may waive one or both requirements above if the recipient shows that it is effectively self-insured against the risks involved. The term “effectively self-insured” means that the recipient has sufficient funds to pay for any damage to the facility, including total replacement if necessary, or to satisfy any liens placed against the facility. If the recipient claims self-insurance, the recipient must provide to NIH assurance that it has sufficient funds available to replace or repair the facility or to satisfy all liens. This assurance should state the source of the funds, such as the organization’s endowment or other special funds set aside specifically for this purpose.

10.6.4 Use of Facility and Disposition

NIH construction grants require that the facility be used for biomedical or behavioral research for as long as needed for that purpose for the period prescribed in the NoA. The date of beneficial occupancy is the date that a facility constructed or modernized with NIH grant support conforming to the design and specifications approved by NIH are available for occupancy and fully operational to carry out all intended facility/research activities. During that time, the recipient must use the facility for the originally authorized purpose unless it obtains prior approval from the NIH awarding IC to use the facility for an alternate purpose. To ensure a recipient’s compliance with the facility usage requirement, the IC GMO will periodically (e.g., at least every two years) survey the recipient throughout the usage period and request a self-certification concerning continued use. NIH may also obtain the names of the investigator(s) occupying the space and an indication of their research interests. Most of the monitoring will be accomplished in this manner. However, NIH staff may perform periodic site visits to observe the use of the grant-sup-

ported space throughout the usage period. After the required usage period, NIH will no longer directly monitor the use of the space.

When use and disposition conditions apply to real property supported under an NIH award, the recipient may not convey, transfer, assign, mortgage, lease, or in any other manner encumber such property without the prior written approval from the awarding office. If the recipient decides that the grant-support space is no longer needed before the expiration of the period of Federal interest, the recipient must request written disposition instruction from the awarding office. This action must be done prior to the recipient's making any irreversible commitment related to property disposition. In this case, NIH may consider an alternate use of the facility or provide disposition instructions.

In determining whether to approve an alternate use of the facility, NIH will take into consideration the extent to which the facility will be used for:

- Other health-related purposes consistent with the authorizing legislation of the program.
- Other health-related activities that are consistent with the mission of the IC; or
- Training and instruction in health fields for health professionals or health-related information programs for the public.

The usage obligation may also be transferred to another facility with the prior approval of NIH. If approved, the remaining usage obligation shall be released from the original facility constructed with grant funds and transferred to the new facility. The recipient remains subject to all other requirements imposed by the NoA or successor document (if the change occurs following the period of grant support).

For disposition of property acquired on an amortized acquisition basis, the computation of the Federal share of real property acquired with long-term debt financing will be computed for each year of grant support in which Federal funds are used to meet all or a portion of the down payment and/or principal on the mortgage.

10.6.5 Real Estate Appraisals

If a real estate transaction funded in whole or in part by NIH requires the use of a real estate appraisal (including, but not limited, to appraisals to determine the Federal share of real property and appraisals to determine required insurance levels), the appraisal must be performed by appraisers certified or licensed by the applicable State in accordance with the requirements established by Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (Public Law 101-73).

10.7 ALLOWABLE AND UNALLOWABLE COSTS AND ACTIVITIES

The following lists indicate types of costs and activities generally allowable and unallowable under NIH construction or modernization grants and major A&R projects unless otherwise noted in the FOA. The lists are not all-inclusive. Program guidelines, the NoA, and other terms and conditions of the award should be consulted for the specific costs allowable under a particular program or grant.

Major A&R is unallowable under foreign grants and foreign components in domestic grants.

The allowability and unallowability of costs and activities applies to the use of Federal funds and funds expended by the recipient to satisfy a matching requirement (see Matching Requirement in this chapter).

Allowable costs and activities include the following:

- Acquisition and installation of fixed equipment.
- Appraisals
- Architectural and engineering services. Also see Pre-award costs below.
- Bid advertising
- Bid guarantees and performance and payment bonds. Bid guarantees and performance and payment bonds are allowable as provided in 2 CFR Part 200.326 and 45 CFR Part 75.334 and 2 CFR Part 200.427 and 45 CFR Part 75.427. A bid guarantee is a form of security assuring that the bidder will not withdraw a bid within the period specified for acceptance and will execute a written contract and furnish required bonds. Performance bonds secure fulfillment of all the contractor's obligations under the contract and payment bonds assure payment as required by law to all persons supplying labor and material in the execution of the work provided for in the contract.
- Contingency fund. To provide for unanticipated costs, applicants for construction grants may include a project contingency amount with the initial total allowable cost estimates. Contingency funds will be limited to 15 percent of the total allowable costs before bids are received and must be reduced to 10 percent after a construction contract has been awarded. NIH may maintain control up to 3% of the total contingency for unanticipated program specific changes during the course of the project.
- Filing fees for recording the NFI. See Real Property Management Standards—Notice of Federal Interest in this chapter.
- Force Account Labor. If the recipient's own construction and maintenance staffs are used in carrying out construction or modernization activities (i.e., force account), the associated costs are allowable provided the recipient can document that a force account is less expensive than if the project were competitively bid and can substantiate all costs with appropriate receipts for the purchase of materials and certified pay records for the labor involved. This requires prior approval by the NIH awarding IC.
- General conditions (e.g. moveable site trailers, port-a-johns, hard hats, temporary or limited duration signage, security costs during construction).
- Inspection and commissioning fees.
- Insurance. Costs of builders risk insurance, title insurance, physical destruction insurance, and liability insurance are generally allowable. Physical destruction, and liability insurance usually are treated as F&A costs but may be treated as direct costs in accordance with the established policy of the recipient, consistently applied regardless of the source of funds. Builder's risk insurance and title insurance may be charged to the grant in proportion to the amount of NIH participation in the property (see Real Property Management Standards—Insurance Requirements in this chapter).
- Legal fees. Legal fees related to obtaining a legal opinion regarding title to a site.
- Pre-award costs. Costs incurred before award for architect's fees, consultant's fees and environmental analysis necessary to the planning and design of the project are allowable if the project is subsequently approved and funded. Pre-award construction or modernization costs are generally unallowable unless NIH grants an exception.
- Profit/fee for contractors/subcontractors. Allowable as part of the overall cost/price of a contract consistent with commercial practice.

- Project management.
- Relocation expenses related to the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (49 CFR Part 24).
- Sidewalks necessary for use of facility.
- Site survey and soil investigation.
- Site clearance. Site clearance costs are allowable as long as they are reflected in the bid.
- Threat-risk assessment. Costs incurred for a site-specific or project-specific assessment of security risk by a qualified professional are allowable.
- NEPA and historic preservation analysis. Costs associated with evaluation of the environmental effects and historic preservation effects of proposed construction, modernization, or A&R activity and obtaining public input, producing the necessary studies, analysis, and resultant reports are allowable. Also see Pre-award costs above.

Unallowable costs and activities include the following:

- Bonus payments to contractors. Bonus payments other than earned incentive payments to contractors under formal incentive arrangements are unallowable. An incentive arrangement is used to motivate contractors to provide required supplies or services at lower costs and, in certain instances, with improved delivery or technical performance, by relating the amount of profit or fee payable under the contract to the contractor's performance.
- Construction of shell space designed for completion at a future date.
- Consultant fees not related to actual construction.
- Damage judgment suits.
- Equipment purchased through a conditional sales contract. A conditional sale is a type of agreement to sell under which the seller retains title to goods sold and delivered to a purchaser until full payment has been made.
- F&A costs.
- Fund-raising expenses.
- Interior and exterior decorating fees (e.g. purchase of artwork, sculpture, etc).
- Land acquisition.
- Landscaping and irrigation costs.
- Legal services not related to title certification.
- Movable equipment.
- Off-site improvements. Off-site improvements, such as parking lots, are not allowable.

10.8 ADMINISTRATIVE REQUIREMENTS

10.8.1 Prior Approval Requirements

Recipients must obtain written prior approval from the GMO for the following types of recipient-initiated project or budget changes:

- Any applicable change as specified in Administrative Requirements—Changes in Project and Budget in IIA.
- Revision that would result in a change in scope of the project, change in project site and/or location, including proposed modifications that would materially alter the costs of the project, space utilization, or financial outlay (including Federal/non-Federal cost share adjustments), resulting in changes in the previously approved procurement method or contract. Modifications that would materially alter the costs include the transfer of funds between construction and non-construction work.
- Deviations from design requirements.
- Alternate contracting methods.
- Revision that would increase the amount of Federal funds needed to complete the project.
- Extension of the project period with or without funds.
- Change in the use of the facility (see Real Property Standards—Use of Facility and Disposition in this chapter).
- Transfer of the remaining usage obligation to another facility.

The request for approval must include sufficient information to allow NIH review of the circumstance(s) and need for the proposed change. For changes affecting construction contracts, if the recipient receives written prior approval from the GMO, the recipient may make or authorize the approved modifications to the construction contract. Minor modifications to construction contracts may be made without NIH awarding IC prior approval. However, copies of all change orders to construction contracts must be retained as grant-related records (see Administrative Requirements—Monitoring—Record Retention and Access in IIA).

10.8.2 Alteration and Renovation Projects Under Non-construction Grants

Two copies of each of the following documents must be submitted with each request for approval of minor A&R projects whether proposed in the application or as a post-award rebudgeting request:

- Single-line drawing of the existing space and proposed alterations.
- Narrative description of the proposed functional utilization of the space and equipment requirements prepared by the program and administrative managers who will use and be responsible for the working space and, when appropriate, with input from architectural and engineering advisors. Final drawings and specifications will be based on this description. The description must include a detailed explanation of the need, character, and extent of the functions to be housed in the space proposed for A&R, using the following headings, as appropriate:
    - General information
    - Description of the functions to be performed in the space
    - Space schedule (detailed description of floor space)
    - List of fixed equipment proposed for the facility
    - Cost estimate (see sample format in Exhibit 8)
    - Special design problems
    - Description of the existing and proposed utility systems for the modified space
    - Description of plans to provide accessibility for the physically handicapped
    - Provisions for meeting the requirements of the Life Safety Code
    - Length of the property lease if the space is rented
    - Other information required by program legislation or regulations.

When the proposed alteration is to occur in a building that is under construction or in an incomplete structure, two copies of the following documentation also must be provided:

- Detailed justification for the need to perform the work before the building is completed
- Cost comparison between doing the work before and after the building is completed
- Description of other specific benefits to be gained by doing the work before the building is completed.

Applicants/recipients undertaking major A&R projects are subject to the review, approval, and documentation requirements included or referenced in this chapter for construction grants.

10.9 CLOSEOUT

Immediately upon completion of construction, modernization, or alteration under a major A&R project the recipient should contact the awarding IC GMO. Under construction grants, the recipient will generally be required to submit the following documents within 120 days following the completion of the project as part of the closeout process:

- A final tabulation of net assignable space supported under the award for each program activity.
- The actual cost of construction per gross and net square foot/meter.
- The actual total allowable project costs after construction per gross and net square foot/meter.
- Actual date of beneficial occupancy of the facility.
- A simplified floor plan or space assignment drawing in electronic format clearly marked to identify the grant-supported space.
- Final record as-built construction documents.

- Electronic submission of the FFR reflecting both the Federal and non-Federal share of outlays when matching is required.
- A written assurance signed by the AOR stating that the recipient has the required insurance coverage and agrees to maintain the required insurance for the applicable duration of the Federal interest in the property or an indication that the recipient is self-insured against the risks involved and the source of funds.

10.10 PUBLIC POLICY REQUIREMENTS

In addition to the public policy requirements and objectives specified in IIA, grants for construction, modernization or major A&R projects are subject to the public policy requirements in this section. These requirements may be specified by statute, regulation, executive order, or policy, and apply regardless of the type of recipient. Exhibit 11 may be used as guidance; however, some of the requirements for construction or modernization grants or major A&R activities may not be applicable to your project or program. Specific questions about whether a particular requirement applies should be directed to the GMO of the awarding IC. Recipients of construction or modernization grants and funding for major A&R projects also must require contractors and subcontractors providing construction services to comply with certain Federal labor standards. These labor standards are discussed in Equal Employment Opportunity and Labor Standards in this chapter. Following are highlights of public policy requirements:

- ***Architectural Barriers Act of 1968, as amended (42 U.S.C. §§ 4151 et seq.).*** The Architectural Barriers Act of 1968, as amended, the Federal Property Management Regulations 101-19.6 (41 CFR Part 101-19.6), and the Uniform Federal Accessibility Standards issued by the General Services Administration (41 CFR Part 101-19.6, Appendix A) set forth requirements to make facilities accessible to, and usable by, the physically handicapped and include minimum design standards. All new facilities constructed with NIH grant support must comply with these requirements. These minimum standards must be included in the specifications for any NIH-funded new construction unless the recipient proposes to substitute standards that meet or exceed these standards. Where NIH assistance is provided for alteration or renovation (including modernization) of existing facilities, the altered facility (or part of the facility) must comply, including use of the minimum standards in the specifications. The recipient will be responsible for conducting inspections to ensure compliance with these standards by any contractor performing construction services under the grant.
- ***Clean Air Act (42 U.S.C. 7401 et seq.), and Federal Water Pollution Control Act (Clean Water Act), as amended (33 U.S.C. 1251 et seq.).*** Provide for the protection and enhancement of the quality of the nation's air resources to promote public health and welfare, and for restoring and maintaining the chemical, physical and biological integrity of the nation's waters; for contracts exceeding $100,000.
- ***Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.).*** Assurance of project consistency with the approved State management program developed under the Act.
- ***Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874).*** When required by statute.
- ***Davis-Bacon Act (40 U.S.C. §§276a to 276a-7).*** When required by statute.

- ***Earthquake Hazards Reduction Act of 1977, as amended (Public Law 95-124), and EO 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990).*** Apply to NIH-assisted construction located in the applicable geographic location. The EO requires that new federally assisted or regulated buildings be designed and constructed using appropriate seismic standards compliant with State, country, or local jurisdictional building ordinances. Where necessary, special structural and other features to protect life and minimize damage to facilities from tornadoes also may be required.
- ***Endangered Species Act of 1973, as amended (P.L. 93-205).*** For the protection of endangered species.
- ***Flood Disaster Protection Act of 1973 - Flood Insurance - The Flood Disaster Protection Act of 1973, as amended (Public Law 93-234).*** Provides that no Federal financial assistance to acquire, modernize, or construct property may be provided in identified flood-prone communities in the United States, unless the community participates in the National Flood Insurance Program and flood insurance is purchased within 1 year of the identification. Lists of flood-prone areas that are eligible for flood insurance are published in the Federal Register by FEMA.
- ***Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.).*** Prohibits the use of lead-based paint in construction or rehabilitation of residence structures.
- ***National Environmental Policy Act of 1969 - NEPA, as amended (Public Law 91-190).*** Establishes national policy goals and procedures to protect and enhance the environment, including protection against natural disasters. NEPA requires all Federal agencies to consider the reasonably foreseeable environmental consequences of any major Federal activity, including grant-supported activities. If NIH determines that NEPA applies to grant-supported activities, NIH will require that the environmental aspects of the activity be reviewed and evaluated by NIH technical staff before final action on the application. This determination also includes determinations concerning floodplain management pursuant to EO 11988, Floodplain Management (May 24, 1977) (42 FR 26951, 3 CFR Part, 1977 Comp., p. 117) and EO 11990, Protection of Wetlands (May 24, 1977) (42 FR 26961, 3 CFR, 1977 Comp., p. 121).

Because projects for construction, modernization, or major A&R activities have the potential to affect the environment, NIH requires that applicants for this type of support provide information on anticipated environmental impact as part of their just-in-time submission. Applicants may use the Review of Environmental and Other Impacts document to supply this information. An alternate format can be used as long as equivalent environmental and other impacts information is provided.

NIH will review the Environmental and Other Impacts information contained in the application to assess the level of environmental impact of the proposed project. It is the responsibility of NIH to determine which of the following will apply to the proposed project:

- ***Environmental Impact Statement (EIS).*** A document required of federal agencies by the NEPA for major projects or legislative proposals significantly affecting the environment. A tool for decision making, it describes the positive and negative effects of the undertaking and considers alternatives.
- ***Environmental Assessment (EA).*** An environmental analysis prepared pursuant to the NEPA to determine whether a federal action would significantly affect the environment and thus require a more detailed environmental impact statement.
- No Further Action is Required.

If NIH determines that an EA or an EIS is required, the applicant (recipient) must conduct the appropriate environmental review and provide the necessary documentation to NIH for review, approval, and

processing. NIH will provide advice and assistance to the applicant (recipient), as necessary, concerning review procedures; evaluate the results of the review; and make the final decision on environmental impact as required by NEPA.

Applicants also must (1) provide a current listing and copies, as applicable, of all relevant licenses, permits, and/or other approvals required including, but not limited to, the State and local air, water quality, and zoning board reports, and (2) indicate the State, local, and regional planning authorities contacted or consulted regarding the application and briefly discuss the proposed facility with respect to regional development plans.

Applicants are not required to incur costs for extensive consultant services at the application stage; therefore, hiring of consultants to develop detailed data and elaborate presentations is discouraged and such costs generally will not be allowable as pre-award costs.

- ***Public Disclosure - Section 102 of NEPA and EO 11514.*** Section 102 of NEPA and EO 11514 (March 5, 1970) provide for public comment and participation in the environmental impact review process. When there is an environmental impact (in accord with NEPA), the applicant must publicly disclose the project in a newspaper or other publicly available medium and to describe any environmental impacts that affect the protection and enhancement of environmental quality concurrent with notification to the SPOC (see Public Policy Requirements—Executive Orders—Intergovernmental Review of Programs under Executive Order 12372 in this chapter). An example of a sample disclosure statement follows:

  "Notice is hereby given that the Uptown Medical School proposes to construct additional space, partially utilizing Federal funds. The proposed construction project is the addition of 251 net square meters connected to the existing Allen Building, which is located at 5333 Main Street, Downtown, Ohio.

  The Medical School has evaluated the environmental and community impact of the proposed construction. There will be (appropriate text will describe impact). The Medical School anticipates that no significant permanent environmental impacts are foreseen, however, this determination is ultimately the responsibility of the awarding Federal agency. In accordance with Executive Order 11514 (March 5, 1970), which implements the National Environmental Policy Act of 1969, as amended, any individual or group may comment on, or request information concerning, the environmental implications of the proposed project. Communications should be addressed to the Office of Planning, Uptown Medical School, and must be received by (date). The Federal grant application may be reviewed at the Office of the Dean, School of Medicine, 5333 Main Street, during normal working hours."

- ***National Historic Preservation Act of 1966 and Archaeological and Historic Preservation Act of 1974.*** Under the provisions of the National Historic Preservation Act, as amended (16 U.S.C. 470 et seq.), and the Archaeological and Historic Preservation Act of 1974, as amended (16 U.S.C. 469a-1 et seq.), the Secretary of the Interior has compiled a National Register of Historic Places—sites and buildings of significant importance to U.S. history. These statutes require that, before approval of a grant related activity, NIH take into account the effect on these sites of the proposed activity. NIH is primarily responsible for determining whether activities will affect a property listed in the National Register or one that meets the eligibility criteria for inclusion, even if not included in the National Register at the time the application is submitted. The National Register of Historic Places may be obtained from the State Liaison Officers designated by their respective states to administer this program or from the Advisory Council on Historic Preservation. The National Trust for Historic Preservation is at http://www.nationaltrust.org/.

If an eligible or potentially eligible historic property will be affected, the applicant must obtain clearance from both the appropriate State Historic Preservation Office and Tribal Historic Preservation Office before submitting the application. Failure to obtain this clearance will delay NIH action on an application. The State Historic Preservation Liaison Officer or the National Trust for Historic Preservation may be contacted for additional details.

- ***Rehabilitation Act of 1973.*** The HHS implementation of section 504 of the Rehabilitation Act of 1973 is found in 45 CFR Part 84, Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance. Section 504 is designed to eliminate discrimination on the basis of handicap in any program or activity receiving Federal financial assistance. Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such manner that the facility or part of the facility is readily accessible to and usable by handicapped persons. Furthermore, each facility or part of a facility which is modernized or altered by, on behalf of, or for the use of a recipient in a manner that affects or could affect the usability of the facility or part of the facility shall, to the maximum extent feasible, be modernized or altered in such manner that the altered portion of the facility is readily accessible to and usable by handicapped persons. Design, construction, or alteration of buildings shall conform to the Federal Property Management Regulations at 41 CFR Part 102 subchapter C, Real Property, Part 102-76.
- ***Safe Drinking Water Act (Title XIV of the Public Health Service Act, as amended).*** For the protection of underground sources of drinking water.
- ***Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Uniform Relocation Act).*** HHS requirements for complying with the Uniform Relocation Act are set forth in 49 CFR Part 24. Uniform relocation assistance and real property acquisition for Federal and federally assisted programs. The Uniform Relocation Act, 42 U.S.C. 4601 et seq., applies to all programs or projects undertaken by Federal agencies or with Federal financial assistance that cause the displacement of any person. The HHS requirements for complying with the Uniform Relocation Act are set forth in 45 CFR Part 15, which references 49 CFR Part 24. Those regulations provide policies and procedures for the acquisition of real property, including acquisition by recipients, and require that displaced people be treated fairly and equitably. They encourage acquiring entities to negotiate promptly and amicably with property owners so property owners' interests are protected and litigation can be avoided.
- ***Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.).*** Related to protecting components or potential components of the national wild and scenic rivers system.

10.10.1 Executive Orders

- ***Intergovernmental Review of Federal Programs (July 14, 1982), as amended, under Executive Order 12372.*** EO 12372 requires consultation with State and local officials on certain proposed Federal assistance. For HHS, these requirements are the Intergovernmental Review of Department of Health and Human Services Programs and Activities. NIH construction and modernization grants are subject to these requirements. Applicants from states that have chosen to participate in the intergovernmental review process should contact their SPOC as early as possible to alert the SPOC to the planned application and to obtain necessary instruction on the State process. Indian tribes (or "federally recognized Indian tribes") are not subject to these requirements.

  SPOCs are given 60 days to review applications. To accommodate this time frame and the NIH review process, an applicant must provide a copy of the application to the SPOC no later than the

time the application is submitted to NIH. SPOC comments must be submitted to NIH with the application, or the application must indicate the date on which the application was provided to the SPOC for review. If SPOC comments are not submitted with the application, the applicant must provide them upon receipt and may include its reaction to the comments, or it must notify NIH that it did not receive any SPOC response.

- ***Executive Order 11988, Floodplain Management (May 24, 1977) (42 FR 26951, 3 CFR, 1977 Comp., p. 117).*** Uneconomical, hazardous, or unnecessary use of flood plains for construction.
- ***Executive Order 11990, Protection of Wetlands (May 24, 1977).*** See 42 FR 26961, 3 CFR, 1977 Comp., p. 121.
- ***Executive Order 12185, Conservation of Petroleum and Natural Gas (Dec. 17, 1979).*** See 44 FR 75093, 3 CFR, 1979 Comp., p. 474.
- ***Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990).*** See 3 CFR, 1990 Comp., p. 269. See Earthquake Hazards Reduction Act bullet in the Construction—Public Policy Requirements section.
- ***Executive Order 12770 - Metric System.*** Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs. All construction, modernization, or A&R (major or minor) supported by NIH grant funds must be designed using the metric system.

Exhibit 11. Summary of Requirements Applicable to Construction, Modernization, and Major A&R Activities

Program Regulation

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
NIH Construction Grants Regulations (42 CFR Part 52b)	Applicable	Applicable	Applicable to major A&R under a research project grant; does not apply to minor A&R funded under an NIH Center grant.

Public Policy Requirements

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Architectural Barriers Act of 1968	Applicable	Applicable	Applicable
Clean Air and Clean Water Act	Applicable	Applicable	Applicable
Coastal Zone Management Act of 1972	Applicable	Applicable	Applicable
Copeland Act	As required by statute	As required by statute	As required by statute
Davis-Bacon Act	As required by statute	As required by statute	As required by statute

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Earthquake Hazards Reduction Act of 1977	Applicable	N/A	N/A
Endangered Species Act of 1973	Applicable	Applicable	Applicable
Flood Disaster Protection Act of 1973	Applicable	N/A	N/A
Lead-Based Paint Poisoning Prevention Act	Applicable	Applicable	Applicable
National Environmental Policy Act (NEPA) of 1969	Applicable	Applicable	As specified by NIH
Public Disclosure - Section 102 of NEPA and EO 11514 (as applicable for the protection and enhancement of environmental quality)	Applicable when the project involves an environmental impact	Applicable when the project involves an environmental impact	Applicable when the project involves an environmental impact
Rehabilitation Act of 1973 (45 CFR Part 84)	Applicable	Applicable	Applicable
Safe Drinking Water Act	Applicable	Applicable	Applicable
Uniform Relocation Act (49 CFR Part 24)	Applicable	N/A	N/A
Wild and Scenic Rivers Act of 1968	Applicable	Applicable	Applicable

Executive Orders

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Executive Order 12372, Intergovernmental Review of Federal Programs	Applicable	Specified in the FOA	Applicable
Executive Order 11988, Floodplain Management	Applicable	Applicable	Applicable
Executive Order 11990, Protection of Wetlands	Applicable	Applicable	Applicable

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Executive Order 12185, Conservation of Petroleum and Natural Gas	Applicable	Applicable	Applicable
Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction	Applicable	N/A	N/A
Executive Order 12770, Metric System	Applicable	Applicable	Applicable

Other Requirements

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Matching	Specified in the FOA and NoA	Specified in the FOA and NoA	N/A
NIH Design Requirements Manual	Applicable	Specified in the FOA	Applicable
Design Documentation Requirements	Applicable	Applicable	Applicable

Procurement Requirement

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Liquidated Damages	Applicable	Applicable	Applicable

Equal Employment Opportunity and Labor Standards

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Equal Employment Opportunity	Applicable	Applicable	Applicable
Nonsegregated Facilities	Contracts exceeding $10,000	Contracts exceeding $10,000	Contracts exceeding $10,000
Contract Work Hours and Safety Standards	Contracts exceeding $100,000	Contracts exceeding $100,000	Contracts exceeding $100,000

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Disposition of Unclaimed Wages	Applicable	Applicable	Applicable

Real Property Standards

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Real Property Management Standards	Applicable	Applicable	Applicable
Notice of Federal Interest	Applicable	Applicable	Applicable
Title Insurance	Applicable unless waived	Applicable unless waived	Applicable unless waived
Physical Destruction Insurance	Applicable unless waived	Applicable unles waived	Applicable unless waived
Use of Facility and Disposition	Specified in the FOA and NoA	Specified in the FOA and NoA or 2 CFR Part 200.311 and 45 CFR Part 75.318	As specified by NIH in accordance with 2 CFR Part 200.311 and 45 CFR Part 75.318

Closeout

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Final Record As-built Construction Documents	Applicable	Applicable	N/A

11 RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS

11.1 GENERAL

This chapter includes general information about Kirschstein-NRSA individual fellowships and institutional research training grants. Separate but all inclusive sections are provided for each; therefore some information may appear duplicative but is provided separately so that nuances between individual fellowships and institutional training grants are covered. Many of the requirements of IIA also apply; this chapter of IIB includes appropriate cross-references to IIA when applicable.

11.1.1 Background

Section 487 of the PHS Act (42 U.S.C. 288) provides authority for NIH to award Kirschstein-NRSA individual fellowships to support predoctoral and postdoctoral training of individuals to undertake biomedical, behavioral, or clinical research at domestic and foreign, public and private institutions (profit and non-profit). Section 487(a)(1)(B) authorizes Kirschstein-NRSA institutional research training grants and limits institutional Kirschstein-NRSA support to training and research at domestic public and nonprofit private entities. The legislation requires postdoctoral NRSA recipients to pay back to the Federal government their initial 12 months of Kirschstein-NRSA postdoctoral support by engaging in health-related biomedical, behavioral and/or clinical research, health related research training, health-related teaching, or any combination of these activities. (See Payback Requirements in this chapter.) The regulations at 42 CFR Part 66 apply to these awards.

11.1.2 Nondiscrimination

The Kirschstein-NRSA program is conducted in compliance with applicable laws that provide that no person shall, on the grounds of race, color, national origin, handicap, or age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity (or, on the basis of sex, with respect to any education program or activity) receiving Federal assistance. Applicant organizations are required to have appropriate Assurance of Compliance forms filed with HHS's OCR before a grant may be made to that institution. The NIH awarding IC should be contacted if there are any questions concerning compliance. (See Public Policy Requirements and Objectives—Civil Rights in IIA for detailed requirements.)

11.2 INDIVIDUAL FELLOWSHIPS

11.2.1 General

The Kirschstein-NRSA program helps ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical, behavioral, and clinical research agenda. Fellowship activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH mission. Under this authority, NIH awards individual postdoctoral fellowships (F32) to promising applicants with the potential to become productive, independent investigators in fields related to the mission of the NIH ICs. Individual pre-doctoral fellowships for research doctoral dissertation training (F31), Individual pre-doctoral fellowships for MD/PhD and other dual clinical/research doctoral training (F30), and

Senior Fellowships (F33), are also provided under this authority. For individual pre-doctoral fellowships, NIH ICs have differing requirements; specific FOAs should be consulted for guidance.

Kirschstein-NRSA fellowships are awarded as a result of national competition for research training in specified health-related areas. All NIH ICs have authority to award Kirschstein-NRSA fellowships. FIC and NLM also have unique funding authorities for fellowships that are not under the Kirschstein-NRSA authority.

11.2.2 Eligibility

11.2.2.1 Research Areas

Kirschstein-NRSA fellowships may be made for research training in areas that fall within the missions of the NIH ICs. Applications that do not address these areas will be returned. An increased emphasis has been placed on the research training of physicians. The HHS Secretary is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of 2 consecutive years of biomedical, behavioral, or clinical research training. NIH recognizes the critical importance of training clinicians to become researchers and encourages them to apply. For those who have a doctoral-level health professional degree, the proposed training may be used to satisfy a portion of the degree requirements for a master's degree, a doctoral degree, or any other advanced research degree program.

11.2.2.2 Research Training Program

The Kirschstein-NRSA fellowship must be used to support a program of research training. It may not support studies leading to M.D., D.O., D.D.S., D.V.M., or other similar clinical, health professional degrees except when those studies are part of a formal combined research degree program such as the M.D./Ph.D. Similarly Kirschstein-NRSA fellowships may not support the clinical portion of residency training. Research fellows in clinical areas are expected to devote full time effort to the proposed research training and to confine clinical duties to those that are part of the research training.

11.2.2.3 Degree Requirements

Predoctoral Training. Individuals must have received, as of the activation date of their Kirschstein-NRSA pre-doctoral fellowship award, a baccalaureate degree or equivalent and must be enrolled in and training at the postbaccalaureate level in a program leading to the award of a Ph.D. or equivalent research degree program (e.g., Eng.D., D.N.Sc., Dr.P.H., D.S.W., Pharm.D, Sc.D.), a formally combined MD/PhD, or other combined professional/clinical and research doctoral program (eg., D.O./Ph.D., D.D.S./Ph.D., D.V.M./Ph.D.) in the biomedical, behavioral, or clinical sciences.

Postdoctoral Training. Before a Kirschstein-NRSA postdoctoral fellowship award can be activated, individuals must have received a Ph.D., M.D., D.D.S, D.M.D., D.C., D.O., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.Sc., D.P.T., Pharm.D., N.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign organization. Also acceptable is a statement by an AOR of the degree-granting institution that all degree requirements have been met. It is the responsibility of the sponsoring institution, not NIH, to determine if a foreign degree is equivalent.

Senior Fellows. As of the beginning date of their award, senior fellows must have a doctoral degree (as specified in Postdoctoral training referenced above) and at least 7 subsequent years of relevant research and professional experience. The senior fellowship is awarded to provide opportunities for experienced scientists to make major changes in the direction of their research careers or to broaden their scientific backgrounds by acquiring new research capabilities. In addition, these awards will enable individuals who are beyond the new investigator stage to take time from regular professional responsibilities to

enhance their capabilities to engage in health-related research. Senior fellowships are made for full-time research training. More information on the senior fellowship program can be found in the NIH Kirschstein-NRSA Senior Fellows (F33) program announcement available on the NIH website.

11.2.2.4 Citizenship

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence by the time of award. Noncitizen nationals are individuals, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on their passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the responsibility of the sponsoring institution to follow up and ensure that the individual receives the I-551 before the 6-month expiration date.

An individual expecting to be admitted as a permanent resident by the earliest possible award date listed in the Kirschstein-NRSA individual fellowship program announcement may submit an application for a fellowship. The submission of documentation concerning permanent residency is not required as part of the initial application. Any fellowship applicant selected to receive an award must provide a notarized statement of admission for permanent residence prior to award.

Fellowship applicants who have been lawfully admitted for permanent residence, i.e., have a Permanent Resident Card or other legal verification of such status, should check the Permanent Resident box in the citizenship section on the PHS Fellowship Supplemental Form of the fellowship application. Fellowship applicants who have applied for and have not yet been granted admission as a permanent resident should check the box indicating Permanent Resident of U.S. Pending.

Individuals with a Conditional Permanent Residency Status may still apply for individual fellowships. However, in all cases when permanent residency status is involved, it is the responsibility of the sponsoring institution to assure the individual remains eligible for NRSA support for the period of time of any award.

Individuals with Asylum/Refugee status do not automatically hold a type of permanent residency status; they have the opportunity to apply for permanent residency status once they have been in the U.S. for a period of time. Therefore, individuals with Asylum/Refugee status should only submit an individual fellowship application once they have applied for permanent residency status.

When an application involving Permanent Residency is selected to receive an award, prior to any award being issued, a notarized statement will be required that documents that a licensed notary has seen the individual's valid Permanent Resident Card or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S.

Individuals on temporary or student visas are not eligible to apply for Kirschstein-NRSA individual fellowships unless they have begun the process for becoming a permanent resident and expect to be admitted as a permanent resident by the earliest possible award date.

11.2.2.5 Sponsorship

General. Before submitting a Kirschstein-NRSA individual fellowship application, the fellowship applicant must identify a sponsoring institution and an individual who will serve as a sponsor (also called mentor or supervisor) and supervise the training and research experience. The sponsoring institution may be domestic or foreign, public or private (commercial or non-profit), including NIH intramural programs,

other Federal laboratories, and units of State and local governments. The sponsoring institution is legally responsible for providing facilities for the applicant and financially responsible for the use and disposition of any funds awarded based on the application. The sponsor should be an active investigator in the area of the proposed research who will directly supervise the fellow's research. The sponsor must document in the application the training plan for the applicant as well as the availability of staff, research support, and facilities for high-quality research training. In most cases, postdoctoral fellowships support research training experiences in new settings in order to maximize acquisition of new skills and knowledge. Therefore, postdoctoral fellowship applicants proposing training at their doctoral institution must document thoroughly the opportunity for new training experiences designed to broaden their scientific backgrounds. In addition, the application should propose research experiences that will allow the fellow to acquire new knowledge and/or technical skills that will enhance their potential to become a productive, independent investigator.

Foreign Sponsorship. An individual may request support for training abroad. In such cases, the fellowship applicant is required to provide detailed justification for the foreign training, including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than training in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Foreign training may require additional administrative reviews and will be considered for funding only when the scientific advantages are clear.

11.2.2.6 NIH Employees & Other Federal Sponsorship (Federal Fellows)

Both civil service employees and PHS commissioned officers at NIH and other Federal laboratories are permitted to compete for predoctoral and postdoctoral fellowships. The proposed training should be primarily for career development rather than for the immediate research needs of NIH or the other Federal laboratory. When at an NIH laboratory, the employee's supervisor must disassociate themselves from the review and award process.

An individual at NIH or another Federal laboratory who is supported under an individual fellowship may not also hold an employee position with the Federal Government. Therefore, successful fellowship applicants for predoctoral or postdoctoral awards must either resign from NIH or the other Federal laboratory or take LWOP before activating the award. (There is no obligation or commitment by either the Federal agency or the fellow for future employment upon termination of the fellowship.)

Support provided for Federal fellows is similar to those at non-Federal sponsoring institutions; stipends, tuition (when applicable), and institutional allowance are provided. However, the administration and payment of these fellowships is unique. Specifics are noted in the applicable sections below. This requirement does not apply to employees of facilities that are Government-owned but Contract-operated, as they are not considered Federal laboratories.

11.2.2.7 Individuals on Active Military Duty

NIH does not restrict career military personnel from applying for Kirschstein-NRSA individual fellowship awards while on active military duty. At the time of application, the fellowship applicant's branch of the military service should submit a letter endorsing their application and indicating willingness to continue normal active duty pay and allowances during the period of the requested fellowship. If an award is made, the institutional allowance and necessary tuition and fees permitted on a postdoctoral program will be paid by NIH. However, stipends, health insurance, and travel allowances are not allowable charges to a Kirschstein-NRSA individual fellowship for career military personnel. Payment of concurrent benefits by NIH to active-duty career military recipients is not allowed.

11.2.3 Application Requirements and Due Dates

11.2.3.1 Application

Each fellowship applicant must submit an application based on the application package provided as part of the FOA. Individual fellowship applications are submitted electronically through Grants.gov using an application package that combines form components from the SF424 (R&R) application with the PHS Fellowship Supplemental Form.

The major emphasis of the application should be the research training experience and broadening of scientific competence. The AOR of the sponsoring institution agrees to secure and retain, but need not submit to NIH, the assurance signatures of the fellowship applicant and sponsor. For postdoctoral fellowship applicants, the assurance of the fellowship applicant includes certification that they have read the payback information and will meet any payback provisions required under the law as a condition for accepting the award.

Fellowship applicants and sponsoring institutions must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements; research misconduct; the humane care and use of live vertebrate animals; the inclusion of women, minorities and individuals across the lifespan in study populations; human embryonic stem cells; and recombinant or synthetic nucleic acid research. (For a complete list of applicable requirements, see Exhibit 4, Public Policy Requirements, Objectives and Appropriation Mandates in IIA.)

11.2.3.2 eRA Commons Registration

All fellowship applicants and sponsoring institutions must be registered in the eRA Commons. The fellowship applicant must be assigned the “PI Role” in the eRA Commons. Only the PI Role will provide the fellowship applicant with the appropriate access in the eRA Commons to the application and review information. When a prospective fellowship applicant is submitting an application through a sponsoring institution that is different than their current institution, that individual must be affiliated with the sponsoring institution.

11.2.3.3 ORCID iDs

The requirement for ORCID identifiers will be enforced at the time of application for individual fellowship including the following: F05, F30, F31, F32, F33, F37, F38, F99/K00 and FI2.

eRA system validations will check whether applicants have ORCID iDs and applications will not be accepted unless an ORCID iD is linked to the PD/PI's eRA Commons Personal Profile.

To either link their eRA profiles to existing ORCID accounts or create ORCID profiles and link them back to the eRA Commons, prospective applicants for individual fellowship awards may follow the ORCID link from their Personal Profiles in the eRA Commons.

11.2.3.4 Letters of Reference

As part of an application submission, at least three (but no more than five) letters of reference on behalf the fellowship applicant also must be submitted. Electronic submission of the fellowship application incorporates a separate, yet simultaneous electronic submission process for reference letters through the eRA Commons. Reference letters are submitted directly by the referee through the eRA Commons and not as part of the electronic application submitted through Grant.gov. Reference letters will be joined with the electronic application within the eRA system once an application completes the submission process. Applications that are missing the required letters may be delayed in the review process or not accep-

ted. Applicants must carefully follow the instructions provided in the Individual Fellowship Application Guide. The Application Guide includes specific instructions to be sent to prospective referees.

11.2.3.5 Responsible Conduct of Research

All fellowship applicants must include a plan to obtain instruction in the responsible conduct of research. This plan should document prior instruction in responsible conduct of research during the applicant's current career stage (including the dates of last occurrence) and propose a plan to receive instruction in responsible conduct of research. The plan must address the five instructional components, format, subject matter, faculty participation, duration of instruction, and frequency of instruction, as outlined and explained below. The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the sponsor/mentor in responsible conduct of research instruction must be described. Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process. Further, applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan. For additional instructions, see the specific FOA.

1. ***Format.*** Discussion-based instruction in the responsible conduct of research is expected to remain a key feature of RCR training and to include substantive face-to-face interaction among participants and faculty. However, recognizing that advances in video conferencing now allow for effective "face-to-face" discussions to occur electronically, institutions may wish to consider incorporating video conferencing options into their RCR instruction, provided that those options are utilized in a way that fosters discussion, active learning, engagement, and interaction among the participants. At the same time, video conferencing should not be the sole means for meeting the requirement for RCR instruction, and a plan that employs only video conferencing will not be considered acceptable, except in special instances of short-term training programs or unusual and well-justified circumstances.

2. ***Subject Matter.*** Developments in the conduct of research and a growing understanding of the impact of the broader research environment have led to a recognition that additional topics merit inclusion in discussions of the responsible conduct of research, including below:
    a. conflict of interest – personal, professional, and financial – and conflict of commitment, in allocating time, effort, or other research resources
    b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
    c. mentor / mentee - responsibilities and relationships
    d. safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)
    e. collaborative research including collaborations with industry and investigators and institutions in other countries
    f. peer review, including the responsibility for maintaining confidentiality and security in peer review
    g. data acquisition and analysis; and laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooksh.
    h. secure and ethical data use; data confidentiality, management, sharing, and ownership
    i. research misconduct and policies for handling misconduct
    j. responsible authorship and publication
    k. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research
3. ***Faculty Participation.*** Sponsors and other appropriate faculty are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Sponsors may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors.
4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the fellow, sponsor and other appropriate faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Existing policy and guidance call for RCR instruction to be undertaken at least once during each career stage, and at a frequency of no less than once every four years. As institutions consider how to optimize the timing and delivery of instruction in the responsible conduct of research, they are encouraged to bear in mind the value of ongoing and discipline-specific training as individuals progress in their research careers. For example, while broad-based instruction in the responsible conduct of research is often appropriate early in graduate school; a more tailored, discipline-specific approach may better fit the needs of advanced graduate students and those who have transitioned to postdoctoral status. If advanced students and postdoctorates have been exposed to the full range of topics traditionally included in RCR instruction early in their scientific training, it may make sense for their ongoing and/or subsequent RCR training to focus on subjects most relevant to their fields, and institutions may wish to consider this approach, where applicable.

Information on the nature of the instruction in the responsible conduct of research and the extent of fellow and faculty participation also must be provided in the annual progress report submitted as a prerequisite to receiving non-competing continuation support.

11.2.3.6 Concurrent Applications

An individual may not have two or more competing Kirschstein-NRSA individual fellowship applications pending review concurrently. In addition, CSR will not accept for review any application that is essentially the same as one already reviewed.

11.2.3.7 Receipt Dates

Kirschstein-NRSA individual fellowship applications undergo a review process that takes 5 to 8 months. The annual schedule for application receipt, review, and award can be found in a specific Funding Opportunity Announcement and on NIH's web site.

11.2.4 Review

Each new and renewal application will be evaluated for scientific merit by an NIH SRG.

11.2.4.1 Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the fellowship will enhance the fellowship applicant's potential for a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria (as applicable for the project proposed).

Individual Fellowship programs are training awards and not research awards. Major considerations in the review are the candidate's potential for a productive career, the candidate's need for the proposed training, and the degree to which the research training proposed, the sponsor, and the environment will satisfy those needs.

11.2.4.2 Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. The following review criteria are applicable primarily to F30, F31 and F32 applications. For review criteria pertaining to other individual fellowship applications (e.g., F05, F33), please refer to the specific FOA. The scored criteria are:

- Fellowship Applicant
- Sponsor(s), Collaborator(s), and Consultant(s)

- Research Training Plan
- Training Potential
- Institutional Environment and Commitment to Training

The FOA should be consulted for additional information describing each of the scored review criteria.

11.2.4.3 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards
- Resubmission Applications
- Renewal Applications

The FOA should be consulted for additional information describing each of the relevant additional review criteria.

11.2.4.4 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- Training in the Responsible Conduct of Research
- Select Agents Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period Support
- Foreign Sponsoring Institutions

The FOA should be consulted for additional information describing each of the relevant additional review considerations.

11.2.4.5 Secondary Level of Review

Kirschstein-NRSA individual fellowship applications receive a secondary level of review by IC staff. Criteria used in making award decisions include the SRG's recommendation concerning the overall merit of the application, the relevance of the application to the IC's research training priorities and program balance, and the availability of funds.

11.2.5 Notification of Action

Shortly after the initial review meeting, each fellowship applicant receives an e-mail indicating that the SRG recommendation/impact score is available in the eRA Commons. The fellowship applicant is also notified via an e-mail when the summary statement is available in the eRA Commons.

The PO may notify the fellowship applicant about the final review recommendation. All questions about initial review recommendations and funding possibilities should be directed to the designated IC PO, not to the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons. If the application is under consideration for funding, NIH will request any additional necessary information from the applicant. After all program and administrative issues have been resolved, the NoA will be issued for those selected for funding.

11.2.6 Period of Support

No individual may receive more than 5 years of aggregate Kirschstein-NRSA support at the predoctoral level and 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of Kirschstein-NRSA support from institutional research training grants and individual fellowships. For individual MD/PhD or other dual-doctoral degree fellowships (F30 only), individuals may receive up to 6 years of aggregate Kirchstein-NRSA support at the pre-doctoral level, including any combination of support from institutional research training grants and individual fellowships. Over the total duration of dual degree support, at least 50 percent of the award period must be devoted to graduate research training leading to the doctoral research degree. For F30 applications for dual-degree candidates other than DDS/PhD, DMD/PhD, and AuD/PhD candidates, applicants must have matriculated into a dual-degree program no more than 48 months prior to the due date of the initial (-01) application. For DDS/PhD, DMD/PhD, and AuD/PhD degree candidates to be eligible, an applicant must have matriculated into a dual-degree program and identified a dissertation research project and sponsor(s).

Any exception to the maximum period of support requires a waiver from the NIH awarding IC based on review of a justification from the individual and sponsoring institution. The AOR of the sponsoring institution must make the request in writing to the NIH awarding IC on behalf of the fellow, and must secure and retain, but need not submit to NIH, the fellow and sponsor's signatures. The request must specify the amount of additional support for which approval is sought. Individuals seeking additional support beyond the third year of postdoctoral support are strongly advised to consult with their PO before submitting a waiver request.

Some generally recognized categories under which NIH may grant exceptions include the following:

- ***Physicians/Clinicians.*** Individuals requiring additional time to complete training, either as participants in a combined M.D./Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training. An exception is contingent upon an assurance of the recipient's good academic standing and sufficient justification.
- ***Interruptions (Break in Service).*** Requests for additional time also will be considered if an event unavoidably alters the planned course of the research training, if the interruption has significantly detracted from the nature or quality of the planned research training, and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation, which prevent a fellow from effectively pursuing research training for a significant period of time. Requests for extension of support also will be considered if a short additional period would provide the fellow an opportunity to use an exceptional training resource directly related to the approved research training program.

Requests for additional time that do not arise from either of the above-described circumstances will be considered only if they are accompanied by an exceptionally strong justification.

11.2.7 Full-Time and Part-Time Training

All fellows are required to pursue their research training full time. Full-time is generally defined as devoting at least 40 hours per week to research training activities or as specified by the sponsoring institution in accordance with its own policies.

Part-Time Training. While NRSA fellows are required to pursue training full-time, under certain circumstances, a written request may be submitted to the NIH awarding IC to permit less than full-time training.

Written requests for part-time training will be considered on a case-by-case basis and must be approved by the NIH awarding IC in advance of each budget period. The circumstances requiring part-time training might include medical conditions, disability, or personal or family situations such as a child or elder care. Part-time training will not be approved to accommodate other sources of funding, job opportunities, clinical practice, clinical training, or responsibilities associated with the fellow's position at the sponsoring institution.

Each written request must be signed by the fellow, the AOR and the fellowship sponsor. The request for part-time training must provide a justification of the need for a reduced level of effort and the expected duration of the period of part-time training. The written request also must include an estimate of the expected duration of the period of part-time training and assurances that the fellow intends to return to full-time training when that becomes possible and intends to complete the proposed research training program. In no case will it be permissible for the fellow to be engaged in Kirschstein-NRSA support for less than 50 percent effort. Individuals who must reduce their commitment to less than 50 percent effort must take a leave of absence from Kirschstein-NRSA fellowship support.

NIH will issue a revised NoA with prorated stipend for the period of any approved part-time training. Part-time training may affect the rate of accrual or repayment of the service obligation for postdoctoral fellows.

11.2.8 Initiation of Support

11.2.8.1 Process

The NIH IC will notify the fellowship applicant of the intention to make an award and confirm the plans for the start of fellowship support. The individual may activate the fellowship on or after the Federal; award date of the NoA up to the latest activation date shown in the NoA (generally 6 months after the Federal award date). This timing allows the individual to make arrangements, such as the completion of degree requirements, coordination with the sponsor, and, if necessary, a move to the sponsoring institution. The latest activation date may be extended in unusual circumstances. Written requests for extensions should be submitted to the NIH awarding IC, by the AOR of the sponsoring institution. The sponsoring institution must secure and retain, but need not submit to NIH, signatures of the fellowship applicant and sponsor before the request is submitted to NIH.

The Activation Notice must be submitted to the NIH awarding IC as of the day the individual begins training. A Payback Agreement also must be completed and submitted but only by postdoctoral fellows in their first 12 months of Kirschstein-NRSA postdoctoral support. See Reporting Requirements—Activation Notice and Reporting Requirements—Payback Agreement in this chapter. A stipend may not be paid until the forms are submitted and the fellow begins training. If necessary for payroll purposes, the Activation Notice and Payback Agreement may be submitted up to 30 days before the start date. However, any change in the planned activation start date must be reported immediately to the sponsoring institution's business office and to the NIH awarding IC. If an award is conditioned upon completion of

degree requirements, the fellow must submit, with the Activation Notice, proof of completion by the degree-granting institution.

Generally, individual fellowship support is approved for consecutive years of training. The initial award budget period is usually for 12 months. Subsequent periods of approved fellowship training are consecutive with the first year of support and are usually in 12-month increments (budget periods). Awards for less than 12 months will be prorated accordingly. If a fellow decides not to activate the award, or to terminate early, they must notify the institution's business office, the sponsor, and the NIH awarding IC immediately, in writing. NIH will make any necessary adjustments in the stipend and other costs, including the institutional allowance.

11.2.8.2 Payment

Domestic. Non-Federal sponsoring institutions receive an award for the stipend, institutional allowance, and tuition and fees (when applicable). The institution directly pays the fellow and disburses all other awarded costs.

Federal Laboratories. Fellows training at Federal laboratories are paid stipends directly by the NIH awarding IC through PMS. Reimbursement for appropriate expenditures is coordinated by the NIH awarding IC; however, payment is through PMS. Note, if a fellow is training at a facility that is Government-owned but Contract operated, this is not considered a Federal laboratory. As with other grants to these types of facilities, the sponsoring institution would be the contractor.

Foreign. Fellows training at foreign sites are paid stipends directly by the NIH awarding IC, through PMS. However, the institutional allowance is awarded to and disbursed by the sponsoring institution.

11.2.9 Allowable and Unallowable Costs

11.2.9.1 Pre-award Costs

Pre-award costs to an individual fellowship are limited. Stipends and tuition and fees may not be charged to a fellowship award until a fellow has actually activated the award and the appropriate paperwork submitted to NIH. Therefore, these costs may never be charged as pre-award to an individual fellowship. There are rare occasions when costs associated with the institutional allowance may be allowable as pre-award costs. Sponsoring institutions should consult with the NIH awarding IC when considering a pre-award cost.

11.2.9.2 Stipends

A stipend is provided as a subsistence allowance for Kirschstein-NRSA fellows to help defray living expenses during the research training experience. It is not provided as a condition of employment with either the Federal government or the sponsoring institution. Stipends must be paid in accordance with stipend levels established by NIH, which are based on a 12-month full-time training appointment. In the event of early termination, the stipend will be prorated according to the amount of time spent in training. The sponsoring institution will submit a Termination Notice reflecting the early termination and the NIH awarding IC will issue a revised NoA to decrease approved funding. The sponsoring institution must base its calculations on the applicable stipend level provided by NIH.

11.2.9.3 Stipend Levels

Stipend levels are updated periodically in conjunction with an NIH annual appropriation. When increases are approved, they are published in the *NIH Guide for Grants and Contracts*. Current levels are posted on the NIH Funding Strategies page. The NIH awarding IC will adjust fellowship awards on their anniversary dates to include the currently applicable stipend amount.

General information related to stipends follows:

- ***Predoctoral.*** One stipend level is used for all pre-doctoral candidates, regardless of the level of experience.
- ***Postdoctoral.*** The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience when the award is issued. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the fellow must be paid at that level for the entire grant year. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.
- ***Senior Fellows.*** The amount of the Kirschstein-NRSA stipend to be paid must be commensurate with the base salary or remuneration that the individual receiving the award would have been paid by the institution with which they have permanent affiliation on the Federal award date of the fellowship award. In no case shall the stipend award exceed the current Kirschstein-NRSA stipend limit set by NIH. The level of Kirschstein-NRSA support will take into account concurrent salary support provided by the institution and the policy of the sponsoring institution. NIH support does not provide fringe benefits for senior fellows.

11.2.9.4 Institutional Allowance

NIH awards an institutional allowance to help support the costs of training. The specific levels of allowance for predoctoral and postdoctoral support, including those for individuals training at Federal laboratories, commercial organizations, or foreign organizations, are published in the *NIH Guide for Grants and Contracts*. They also are available on the NIH web site.

The institutional allowance is a fixed amount. Expenditures under institutional allowances are not subject to NIH prior approval requirements, and the institution is not required to account for these expenditures on an actual cost basis. Allowable uses of the Institutional Allowance are described below.

Except for fellows at Federal training sites, consistent with NIH policy governing the type of expenditures appropriate for the institutional allowance, the sponsoring institution authorizes the expenditure of the institutional allowance on behalf of the fellow according to the institution's policy. The institution is entitled to expend up to the full institutional allowance upon official activation of the award. However, if an individual fellow is not in a training status for more than 6 months of the award year, only one-half of that year's institutional allowance may be charged to the grant. The NoA will be revised and the stipend and institutional allowance balances must be refunded to NIH.

For fellows at Federal training sites, the NIH awarding IC authorizes the expenditure of the allowance, and payment is made through PMS.

The type of sponsoring institution dictates what costs may be charged to this category and how the funds are to be administered:

- ***Non-Federal Public and Private Non-Profit Institutions (Domestic and Foreign).*** The allowance is intended to defray expenses for the individual fellow such as research supplies, equipment, travel to scientific meetings, and health insurance and to otherwise offset, insofar as possible, appropriate administrative costs of training. Funds are paid directly to and administered by the sponsoring institution.
- ***Federal Laboratories.*** The allowance is intended to cover the costs of scientific meeting travel, health insurance, and books. Funds are administered by the NIH awarding IC and disbursed through PMS.

- ***For-Profit Institutions.*** The allowance is intended to cover the costs of scientific meeting travel, health insurance, and books. Funds are paid directly to the sponsoring institution for disbursement to the fellow.

The following are guidelines for the use of the institutional allowance:

- ***Travel.*** Payment for travel to scientific meetings is appropriate when it is necessary for the individual's training and when the costs are incurred within the period of grant-supported training.

  For fellows at Federal laboratories, reimbursement of travel costs must be in accordance with applicable Federal travel regulations.

  Funds may not be expended to cover the costs of travel between the fellow's place of residence and the domestic training institution, except that the sponsoring institution may authorize the cost of a one-way travel allowance in an individual case of extreme hardship.

- ***Health Insurance.*** A fellow's health insurance is an allowable cost only if applied consistently to all individuals in a similar training status regardless of the source of support. Family health insurance is an allowable cost for fellows who have families and are eligible for family health insurance coverage at the sponsoring institution. Self-only health insurance is an allowable cost for fellows without families. Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy.
- ***Medical Liability and Other Special Insurance.*** Medical liability (malpractice) insurance or other special insurance is an allowable cost to NRSA grants only if nature of the research training requires such special insurance. For instance, medical liability would be allowable if the research training experience involves direct contact with patients or human subjects. In all cases, for the cost to be charged to the NRSA grant, it must be consistently required for all in a similar training status, regardless of the source of support. Special insurances that are routinely offered as optional employee benefits (such as disability insurance, life insurance, or workman's compensation insurance), are not normally allowable charges (see separate section on Employee Benefits) unless the nature of the research training requires such special insurance.
- ***Extraordinary Costs.*** Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring institution or accommodations for fellows who are disabled, as defined by the Americans with Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution in the application or as part of a special written request.

11.2.9.5 Tuition and Fees

Tuition and fees are provided under the following policy:

- For individual predoctoral fellowships (**F30 and F31**), an amount equal to 60% of the level requested by the sponsoring institution, up to $16,000 per year, will be provided. If the program supports formally combined dual-degree training (e.g., M.D.-Ph.D., D.D.S.-Ph.D.), the amount provided will be up to $21,000 per year. Note the new policy moves health insurance into the Institutional Allowance budget category for predoctoral fellowships. This is now consistent with the treatment of this cost for postdoctoral fellowships

- For individual postdoctoral fellowships (**F32**) and individual senior fellowships (**F33**), an amount equal to 60% of the level requested by the applicant institution, up to $4,500 per year, will be provided. If the program supports postdoctoral individuals in formal degree-granting training, the amount provided will be up to $16,000 per year. For postdoctoral fellows, costs associated with tuition and fees are allowable only if they are required for specific courses in support of the research training. Health insurance is not included in this budget item because costs for it are to be charged as institutional allowance.

11.2.9.6 Travel to Foreign Training Sites

For fellows at foreign training sites, in addition to the institutional allowance, awards may include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement shall not be influenced by factors of cost, convenience, or personal travel preference. Any funds awarded for travel to/from foreign training sites must be reported on the Termination Notice as part of the "Amount of Stipend" column. For additional information regarding foreign travel, see Cost Considerations—Allowability of Costs/Activities-Selected Items of Cost-Travel/Employees in IIA.

11.2.9.7 Childcare Costs

Each full-time NRSA fellow may request $2,500 per budget period to defray childcare costs. Childcare must be provided by a licensed childcare provider. Recipients must maintain all supporting documentation (e.g., proof provider is licensed) and make it available to NIH officials upon request. NIH does not require recipients to submit this supporting documentation with each request.

The NRSA fellow childcare costs are not tied to payback obligations, nor should it be reported as such.

When childcare costs are awarded, they are generally restricted and cannot be re-budgeted without prior written approval from the NIH awarding IC. In cases of early termination, recipients may not use any unused portion of the childcare costs. It will remain unobligated and will be adjusted by the agency as part of the closeout process.

Applicants and recipients may request the NRSA childcare costs as part of new applications, continuation applications (Type 5), or as an administrative supplement request (Type 3).

11.2.9.8 Employee Benefits

Since Kirschstein-NRSA fellowships are not provided as a condition of employment with either the Federal government or the sponsoring institution, institutions may not seek funds, or charge individual fellowship awards, for costs that normally would be associated with employee benefits (for example, Federal Insurance Contributions Act (FICA), which funds Social Security and Medicare, workman's compensation, life insurance, union dues, and unemployment insurance). Concerning union dues or other similar costs otherwise paid personally by the fellow; if a fellow requests the institution deduct such a cost from the stipend amount, the institution can provide the fellow such a service. However, in no case can such a deduction from the stipend be made automatically without the approval of the fellow.

11.2.9.9 Rebudgeting of Funds

Individual fellowship awards are formula based, generally restricted for the specific budget category of the award, and cannot be rebudgeted without prior written approval from the NIH awarding IC.

- Stipends must be expended using the stipend level provided in the award; no funds can be rebudgeted into the stipend category to accommodate a stipend level different from the established NIH level. When a fellowship terminates early, any unexpended stipends must be returned and cannot be rebudgeted into any other budget category.
- Institutional allowance is a fixed amount of money with a number of allowable costs. In the rare case where institutional allowance may be unexpended, it can only be rebudgeted into the tuition and fees category when tuition and fees have been awarded.
- When tuition and fees is awarded, it is generally restricted and cannot be rebudgeted without prior written approval from the NIH awarding IC.

11.2.10 Supplementation of Stipends, Compensation, and Other Income

11.2.10.1 Stipend Supplementation

Kirschstein-NRSA fellows receive stipends to defray living expenses. Stipends may be supplemented by an institution from non-Federal funds provided this supplementation is without any additional obligation for the fellow. An institution can determine the amount of stipend supplementation, if any, it will provide according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may PHS funds be used for supplementation.

An individual may use Federal educational loan funds or VA benefits when permitted by those programs as described in Other Income: Educational Loans or GI Bill in this chapter.

11.2.10.2 Compensation

NIH recognizes that Kirschstein-NRSA fellows may seek part-time employment incidental to their training program to offset further their expenses. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part time research, teaching, or clinical employment, so long as those activities do not interfere with, or lengthen, the duration of their NRSA training. Funds characterized as compensation may be paid to fellows only when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions for compensation of students as detailed in Cost Considerations—Selected Items of Cost—Fringe Benefits / IHE Tuition/Tuition Remission in IIA. In addition, compensation must be in accordance with organizational policies applied consistently to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation (salary, fringe benefits, and/or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. However, NIH expects that compensation from research grants will be for limited part-time employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant that supports the same research that is part of the fellow's planned training experience as approved in the Kirschstein-NRSA individual fellowship application.

Stipend Supplementation & Compensation. Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved Kirschstein-NRSA training program. Fellowship sponsors must approve all instances of

employment on research grants to verify that the circumstances will not detract from or prolong the approved training program.

11.2.10.3 Other Income: Concurrent Benefits

A Kirschstein-NRSA individual fellowship may not be held concurrently with another federally sponsored fellowship or similar Federal or non-Federal award that provides a stipend or otherwise duplicates provisions of the Kirschstein-NRSA.

11.2.10.4 Other Income: Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the VA (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation.

11.2.10.5 Other Income: NIH Loan Repayment Program

Postdoctoral fellows may also be eligible to participate in the NIH Loan Repayment Program.

11.2.10.6 Taxability of Stipends

Section 117 of the Internal Revenue Code (26 U.S.C. 117) applies to the tax treatment of scholarships and fellowships. In general, degree candidates may exclude from gross income (for tax purposes) any amount used for qualified tuition and related expenses such as fees, books, supplies, and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are required to report as gross income any monies paid on their behalf for stipends or any course tuition and fees required for attendance.

The IRS and Treasury Department released regulations in January 2005 (Revenue Procedures 2005-11) clarifying the student exception to the FICA (Social Security and Medicare) taxes for students employed by a school, college, or university where the student is pursuing a course of study. NIH's understanding is that these final regulations do **not** apply to or impact Kirschstein-NRSA programs or awards.

The taxability of stipends in no way alters the relationship between Kirschstein-NRSA fellows and sponsoring institutions. Kirschstein-NRSA stipends are not considered salaries. In addition, recipients of Kirschstein-NRSA individual fellowships are not considered to be in an employee-employer relationship with NIH or the sponsoring institution solely as a result of the Kirschstein-NRSA award. The interpretation and implementation of the tax laws are the domain of the IRS and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

11.2.10.7 Form 1099

Although stipends are not considered salaries, these funds are subject to Federal and, sometimes, State income tax. Such income may be reported by the sponsoring institution on IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the sponsoring institution will be responsible for annually preparing and issuing IRS Form 1099 for fellows paid through the institution (fellows at domestic non-Federal institutions). Sponsoring institutions are not required to issue a Form 1099, but it is a useful form of documentation of funds received and it serves as a reminder to the fellow that some tax liability may exist. Fellows are reminded that, even if the sponsoring institution does not issue a Form 1099, they still are required to report Kirschstein-NRSA stipends. For fellows training at a Federal or foreign laboratory and receiving a stipend from NIH, PMS will issue a Form 1099.

11.2.11 Reporting Requirements

The submission of the forms described in this subsection is critical to establishing and paying stipends and other costs and determining possible payback service. All of these forms are available in PDF-fillable and Word formats. The NIH awarding IC may provide copies of applicable forms with the NoA or reference this web site in the NoA.

11.2.11.1 Activation Notice

The individual may activate the fellowship on or after the issue date of the NoA up to the latest activation date shown in the NoA (generally 6 months after the award issue date).Immediately upon the initiation of training, the individual must complete and sign the Ruth L. Kirschstein Individual Fellowship Activation Notice (Form PHS 416-5), obtain the signature of the AOR, and forward the notice along with the Payback Agreement (required only for postdoctoral fellows in their first 12 months of Kirschstein-NRSA support) to the NIH awarding IC.

For Kirschstein-NRSA fellows paid directly by PMS (i.e., those sponsored by foreign or federal institutions, the Activation Notice is required for the initial year only and should be submitted immediately prior to the initiation of training. For all other Kirschstein-NRSA fellows the form should not be submitted before the fellow actually begins training. Stipend checks are issued when both the Activation Notice and the Payback Agreement (required only for postdoctoral fellows in their first 12 months of Kirschstein-NRSA support) are received by the NIH awarding IC.

The Activation Notice is required for the initial year only. The Activation Notice may be submitted up to 30 days before the individual begins training if necessary for payroll purposes. However, the institution must not release any funds until the individual has started their fellowship training. Furthermore, if the individual does not begin research fellowship training on the day indicated, the institution must notify the NIH awarding IC immediately. Competing continuation awards must be activated on the day following the end of the last budget period of the previous award.

11.2.11.2 Payback Agreement

A Ruth L. Kirschstein National Research Service Award Payback Agreement (Form PHS 6031) that covers the initial 12 months of Kirschstein-NRSA postdoctoral support must be signed by each person who is to receive an individual postdoctoral fellowship. This form is not required if the individual has already received 12 months of postdoctoral Kirschstein-NRSA support under any Kirschstein-NRSA institutional research training grant or fellowship award. For details on Kirschstein-NRSA payback, see Payback Reporting Requirements in this chapter.

No Payback Agreement is required for predoctoral fellows.

11.2.11.3 Termination Notice

The Ruth L. Kirschstein National Research Service Award Termination Notice (Form PHS 416-7) (along with the Activation Notice and the NoA) is the basis for validating the total period of Kirschstein-NRSA support and establishing the amount of payback obligation for each Kirschstein-NRSA fellow. For individual fellowships, a reminder of this reporting requirement may be sent to the fellow by the NIH awarding IC before the scheduled termination date. For early terminations, the completed form will be required immediately upon receipt of notification from the fellow or an AOR.

For individual fellowships training at Foreign training sites, any funds awarded for travel to/from foreign training sites must be reported on the Termination Notice as part of the “Amount of Stipend” column. For individual fellowships training at Federal laboratories, this column should include all monies paid directly to them through PMS (stipend, travel, etc. as awarded).

The termination notice must be submitted within 30 days of the termination date even if the fellow is not available for signature. In most cases, the information on the form must be verified by the sponsor and an institutional business official, however, in cases where the sponsor is not available to sign the Notice within the required timeframe, the form may be verified by the institutional business official alone. The lack of timely and accurate information on this form could adversely affect data collected associated with aggregate NRSA support and the payback process. For additional information on early termination, see Changes in the Project below. All Termination Notices for individual fellowships are required to be submitted electronically using the eRA Commons xTrain application.

11.2.11.4 Consecutive Support

If a fellow switches from one Kirschstein-NRSA grant mechanism to another (e.g., from an institutional research training grant to an individual fellowship or from one NIH IC to another), the requirement for payback service incurred is deferred until the total period of Kirschstein-NRSA support is completed. All fellowship applications are reviewed to determine if previous Kirschstein-NRSA support has been provided.

11.2.11.5 Progress Reports

Annual progress reports must be submitted for non-competing continuation support. The Research Performance Progress Report (RPPR), which is required for fellowship awards, can be accessed from the eRA Commons. The IDP requirement described in Non-Competing Continuation Progress Reports applies to individual fellowships. Inadequate or incomplete progress reports may result in a delay of continued support. For Kirschstein-NRSA individual fellowship awards, the final progress report information is required as part of the Termination Notice.

11.2.11.6 Financial Reporting

An annual or final FFR to report expenditure information is not required for Kirschstein-NRSA individual fellowship awards.

11.2.12 Changes in the Project

Individual fellowship awards are made for training at a specific institution under the guidance of a particular sponsor. The approval of the NIH awarding IC is required for a transfer of the award to another institution, a change in sponsor, or a project change. As part of the approval process, if a fellow sponsored by a domestic non-Federal institution requests a transfer to another domestic non-Federal institution before the end of the current award year, the institutions are responsible for negotiating which institution will pay the stipend until the end of the current year. Disposition of the institutional allowance is also negotiable between the two sponsoring institutions. No Activation Notice is required from the new sponsoring institution.

Transfers involving Federal or foreign sponsoring institutions require unique administrative procedures and approvals. Because each transfer varies depending on individual circumstances, the sponsoring institution should contact the NIH awarding IC for specific guidance.

Any proposed change in the individual's specified area of research training must be reviewed and approved in writing by the NIH awarding IC to ensure that the training continues to be within the scientific scope of the original peer-reviewed application.

When the sponsor plans to be absent for a continuous period of more than 3 months, an interim sponsor must be named by the institution and approved in writing by the NIH awarding IC.

11.2.13 Other Terms and Conditions

11.2.13.1 Leave

Vacations and Holidays. Kirschstein-NRSA fellows may receive the same vacations and holidays available to individuals in comparable training positions at the sponsoring institution. Fellows shall continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters generally is considered an active part of the training period and is not considered to be a vacation or holiday.

Sick leave and Other Leave. Kirschstein-NRSA fellows may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for medical conditions related to pregnancy and childbirth.

Parental Leave. Kirschstein-NRSA fellows may receive stipends for up to *60 calendar days* (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of each child. NRSA trainees and fellows must provide advanced notification to the recipient institution prior to taking parental leave. Notification of supervisors and others about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds. Either parent is eligible for parental leave. The use of parental leave requires approval by the sponsor.

Terminal Leave. A period of terminal leave is not permitted, and payment may not be made from grant funds for leave not taken.

Unpaid Leave. Individuals requiring extended periods of time away from their research training experience, that is, more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding IC for an unpaid leave of absence. A request letter signed by the fellow and fellowship sponsor must be submitted by the AOR, and must advise the NIH awarding IC of the dates of the leave of absence. Upon approval of the request, the NIH awarding IC will issue a revised NoA extending the ending date of the current budget/project period by the appropriate number of days or months of unpaid leave time. Recipients are precluded from spending award funds during the leave of absence; although continued coverage of health insurance would be allowable if in accordance with policy of the sponsoring institution.

During a leave of absence, documentation to suspend the award and/or the accrual of service for calculating the payback obligation must be completed and retained by the sponsoring institution. When the fellowship is eventually terminated, the leave of absence must be clearly documented on the Termination Notice.

11.2.13.2 Termination

NIH may terminate a Kirschstein-NRSA individual fellowship before its scheduled completion date if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. If an award is terminated, NIH will notify the fellow in writing of the determination, the reasons for the determination, the effective date, and the right to appeal the decision.

NIH also may terminate an award at the request of the sponsoring institution or the individual fellow. The NIH awarding IC must be notified immediately if a sponsoring institution wants to terminate an individual fellow or the fellow decides to terminate training before the scheduled completion date.

If a fellow receives another NIH award, e.g., as a PD/PI on an R03, then the fellow is no longer eligible for the fellowship and the sponsoring institution should contact the awarding IC concerning early termination.

If a Kirschstein-NRSA fellowship is terminated early, the stipend must be prorated according to the amount of time spent in training, and the NoA will be revised downward. In addition, if the length of the final budget period was 6 months or less, the balance of any institutional allowance (at least one-half) must be refunded.

11.2.13.3 Publications and Sharing of Research Results

NIH supports the practical application and sharing of outcomes of funded research. Therefore, recipients of Kirschstein-NRSA fellowships should make the results and accomplishments of their activities available to the research community and to the public at large. The sponsoring institution should assist the fellow in such activities, including the further development of discoveries and inventions for furthering research and benefiting the public. No restrictions should be placed on the publication of results.

Kirschstein-NRSA fellows are encouraged to submit reports of their findings to the journals of their choice for publication. Responsibility for direction of the project should not be ascribed to NIH. However, NIH awarding IC support must be acknowledged by a footnote in language similar to the following: "This research was supported by the National Institutes of Health under Ruth L. Kirschstein National Research Service Award (number) from the (name of NIH IC)." In addition, Federal funding must be acknowledged as provided in Appropriation Mandates—Acknowledgment of Federal Funding in IIA.

The Public Access Policy requirements described in Administrative Requirements—Availability of Research Results—NIH Public Access Policy in IIA apply to articles that are authored or co-authored by NRSA fellows and arose from NIH Support. Information on publications is included as part of the annual progress report.

11.2.13.4 Copyright

Except as otherwise provided in the conditions of the award, when a publication or similar copyrightable material is developed from work supported by NIH, the author is free to arrange for copyright without approval of the NIH awarding IC. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce, translate, publish, and use and dispose of such materials, and to authorize others to do so for Federal government purposes.

11.2.13.5 Inventions and Patents

Fellowships funded primarily for educational purposes are not subject to invention reporting requirements nor does NIH have any rights to inventions under those awards (as specified in 37 CFR Part 401.1 (b)). Kirschstein-NRSA fellows training at NIH represent an exception to this policy. Those fellows are subject to the provisions of EO 10096 and NIH determines the disposition of rights to any invention conceived or first actually reduced to practice during the period of the fellowship.

11.2.13.6 Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award must be assigned to the sponsoring institution for disposition in accordance with established organizational policy. The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations, which, if permitted by organizational policy, may be retained by the fellow.

11.2.13.7 Public Policy Requirements and Objectives

All Public Policy Requirements, Objectives, and Other Appropriation Mandates discussed in IIA apply to Individual Kirschstein-NRSA fellowships when appropriate. Applicants must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements and inclusion policies for women, minorities and individuals across the lifespan; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or or synthetic nucleic acid research. See IIA for a complete list of applicable requirements.

It is the sponsoring institution's responsibility to ensure that a fellow has received the proper training/education and is properly supervised particularly in the areas of human subjects research, vertebrate animal research, and occupational safety programs.

Additional information and any application requirements can be found in the Individual Fellowship Application Guide.

Information provided below is in addition to that provided in IIA where unique circumstances might exist for individual fellowships.

11.2.13.7.1 Human Subjects

Indefinite Involvement. If the sponsoring institution has an approved FWA on file with OHRP but, at the time of application, plans for the involvement of human subjects are indefinite, the assurance number should be provided in the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

If the applicant organization does not have an approved FWA with OHRP, one needs to be obtained prior to IRB approval.

11.2.13.7.2 Vertebrate Animals

Indefinite Involvement. If the sponsoring institution has an approved Animal Welfare Assurance on file with OLAW but, at the time of application, its plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, the institution should indicate "Yes," to the involvement of Vertebrate Animals, include the Animal Welfare Assurance number, and indicate "Indefinite." If an award is made, vertebrate animals may not be involved until verification of the IACUC approval date has been submitted to the NIH awarding IC.

If the applicant organization does not have an approved Animal Welfare Assurance on file with OLAW or for additional information on vertebrate animals, refer to the Individual Fellowship Application Guide or contact OLAW (see Part III).

11.2.13.8 Applicability of NIH Standard Terms of Award

Individual Fellowships are awarded under the NIH Standard Terms of Award however the provisions to extend the final budget period of a project period without additional funds and carryover of unobligated balances do not apply.

11.3 INSTITUTIONAL RESEARCH TRAINING GRANTS

11.3.1 General

NIH will award Kirschstein-NRSA institutional research training grants (T32, TL2, T34, and T35) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the

institution, who are training for careers in specified areas of biomedical, behavioral, and clinical research. The purpose of the Kirschstein-NRSA program is to help ensure that a diverse and highly trained workforce is available in adequate numbers and in the appropriate research areas and fields to carry out the nation's biomedical, behavioral, and clinical research agenda. The program shall be carried out in a manner to recruit women and individuals from disadvantaged groups (including racial and ethnic minorities) into biomedical research. Training activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH Mission. The Kirschstein-NRSA training programs support predoctoral, postdoctoral, and short-term research training as well as limited specialized support at the prebaccalaureate level. All NIH ICs except FIC and NLM award Kirschstein-NRSA institutional research training grants. FIC and NLM have unique funding authorities for training grants that are separate from the Kirschstein-NRSA authority.

11.3.2 Eligibility

11.3.2.1 Applicant Eligibility

A domestic, non-profit public or private organization may apply for a grant to support a research training program in a specified area(s) of research. Support for predoctoral, postdoctoral, or a combination of trainees may be requested. (Specific program announcements should be consulted for IC guidelines.) Support for short-term training positions for students in health-professional degree programs also may be requested as indicated in Short-Term Research Training in this subsection. Each applicant institution must submit an application using the research training forms and instructions (see Application Requirements and Due Dates in this subsection).

11.3.2.2 Research Areas

Kirschstein-NRSA institutional research training grants may be made for research training in areas that fall within the missions of the NIH ICs. Applications that do not address these areas will be returned. An increased emphasis has been placed on the research training of physicians. The HHS Secretary is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of 2 consecutive years of biomedical, behavioral, or clinical research training.

The applicant institution must have a strong research program in the areas proposed for research training and must have the staff and facilities required to carry out the proposed program.

Trainees appointed to the training program must have the opportunity to carry out supervised biomedical, behavioral, or clinical research with the primary objective of developing or extending their research skills and knowledge in preparation for a research career.

11.3.2.3 Training Program Director/Principal Investigator(s)

The Training PD/PI must be an individual with the skills, knowledge, and resources necessary to organize and implement a high-quality research training program at the recipient organization. The Training PD/PI at the recipient organization will be responsible for the selection and appointment of trainees to the Kirschstein-NRSA research training grant and for the overall direction, management, and administration of the training program, including program evaluation, and submission of all required forms in a timely manner. In selecting trainees, the PD/PI must make certain that individuals receiving support meet the eligibility requirements set forth in this subsection.

More than one Training PD/PI (or multiple PD/PIs), may be designated on the application for training programs that require a team approach and therefore, clearly do not fit the single-PD/PI model (e.g., interdisciplinary of multidisciplinary training). The decision to apply for a single PD/PI or multiple PD/PIs is

the responsibility of the investigators and applicant organizations, and should be determined and justified by the goals of the training program. Applications for grants with multiple PD/PIs require additional information, including the structure and governance of the PD/PI leadership team. In addition, the knowledge, skills and experience of the individual PD/PIs will be factored into the assessment of the overall scientific merit of the application. Multiple PD/PIs on a program share the authority and responsibility for leading and directing the training program, intellectually and logistically. Each PD/PI is responsible and accountable to the recipient organization for the proper conduct of the program, including the submission of required reports.

Applications reflecting multiple PD/PIs must provide a Leadership Plan. The emphasis in the Leadership Plan should be on how it will benefit the research training program and the trainees.

A single Contact PD/PI must be designated for the purpose of communicating with NIH, although other individuals may contact NIH on behalf of the Contact PD/PI when necessary. Because training programs are intended to be coherent, NIH will not allocate the budget or training positions between multiple PD/PIs. Only a single award will be issued. Multiple PD/PI training programs should include reasonable numbers of PD/PIs and each individual should be included for a specific purpose. Multiple-PD/PI applications should not include all mentors of the training grant as PD/PIs, except in unusual cases.

11.3.2.4 Research Training Program

A Kirschstein-NRSA institutional research training grant must be used to support a program of research training. It may not support studies leading to the M.D., D.D.S., D.V.M., or other clinical, health professional training except when those studies are a part of a formal combined research degree program, such as the M.D./Ph.D. Similarly, trainees may not accept Kirschstein-NRSA support for clinical training that is part of residency training leading to clinical certification in a medical or dental specialty or subspecialty. However, clinicians are permitted and encouraged to engage in Kirschstein-NRSA-supported full-time, postdoctoral research training even when that experience is creditable toward certification by a clinical specialty or subspecialty board.

Research trainees are expected to devote full time to the proposed research training. Full-time is generally defined as devoting at least 40 hours per week to the program or as specified by the sponsoring institution in accordance with its own policies. In order to fulfill the full-time requirement, trainees who also are training as clinicians must confine clinical duties to those that are an integral part of the research training experience.

11.3.2.5 Degree Requirements

11.3.2.5.1 Predoctoral Training

Predoctoral research training is for individuals who have a baccalaureate degree or equivalent and are enrolled in and training at the postbaccalaureate level in a program leading to either a Ph.D., a comparable research doctoral degree, or a combined clinical degree and Ph.D., such as M.D./Ph.D. Students enrolled in health-professional programs that are not part of a formal, combined program (i.e., M.D./Ph.D.), and who wish to postpone their professional studies to gain research experience, also may be appointed to a Kirschstein-NRSA institutional research training grant. Predoctoral research training must emphasize fundamental training in areas of basic biomedical, behavioral, and clinical sciences.

11.3.2.5.2 Postdoctoral Training

Postdoctoral research training is for individuals who have received a Ph.D., M.D., D.D.S., D.M.D., D.C., D.O., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.Sc., D.P.T., Pharm.D., N.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign organization. It is the responsibility

of the recipient institution, not NIH, to determine if a foreign degree is equivalent. Research training at the postdoctoral level must emphasize specialized training to meet national research priorities in the biomedical, behavioral, or clinical sciences.

Kirschstein-NRSA institutional research training grants are a desirable mechanism for the postdoctoral training of physicians and other health professionals who may have had extensive clinical training but limited research experience. For such individuals, the training may be a part of a research degree program. In all cases, health-professional postdoctoral trainees are to engage in at least 2 years of research, research training, or comparable experiences beginning at the time of appointment, since the duration of training has been shown to be strongly correlated with post-training research activity.

11.3.2.5.3 Short-Term Research Training

Short-term research training includes the following:

- ***Students in Health Professional Schools.*** NIH offers two short-term training programs: those that are part of a traditional institutional research training grant (T32) and those that exclusively support short-term trainees (T35). Short-term research training experiences of 2 to 3 months are available to students in health-professional schools under both mechanisms. All short-term training must be full time. Unless otherwise stated, the requirements that apply to institutional research training grants also apply to short-term research training. Current stipend levels are published in the NIH Guide for Grants and Contracts.
- ***T32.*** T32 (Kirschstein NRSA-Institutional Research Training Grant) applications may include a request for short-term positions reserved specifically to provide full-time health-related research training experiences during the summer or other "off-quarter" periods. Such positions are limited to medical students, dental students, students in other health-professional programs, and graduate students in the physical or quantitative sciences. Short-term appointments under institutional research training grants are intended to provide health-professional students with opportunities to participate in biomedical, behavioral, or clinical research in an effort to attract these individuals into research careers.

To be eligible for short-term predoctoral research training positions, students must be enrolled and in good standing and must have completed at least one quarter or semester in a program leading to a clinical doctorate or doctorate degree in a quantitative science, such as physics, mathematics, or engineering, before participating in the program. Individuals already matriculated in a formal research degree program in the health sciences, holding a research doctorate or master's degree, or a combined professional and research doctorate normally are not eligible for short-term training positions. In schools of pharmacy, only candidates for the Pharm. D. degree are eligible for short-term positions.

Short-term positions should be requested in the application. Short-term research training positions should last at least 8, but no more than 12, weeks. Health-professional students and students in the quantitative sciences selected for appointment should be encouraged to obtain multiple periods of short-term, health-related research training during the years leading to their degrees. Such appointments may be consecutive or may be reserved for summers or other "off-quarter" periods.

Since some NIH ICs do not support short-term research training positions under the T32 or support them on a limited basis only, applicants are urged to contact the appropriate NIH IC before requesting short-term research training positions as part of a T32 application.

T35. Several NIH ICs provide short-term research using a separate training grant mechanism (T35). The program intent and student eligibility requirements are similar to those indicated for the T32. However, since this Kirschstein-NRSA funding mechanism is used by only a few NIH ICs; interested applicants are encouraged to contact specific ICs for details.

11.3.2.5.4 Pre-baccalaureate Training

NIH offers distinct programs for pre-baccalaureate training under the auspices of the Kirschstein-NRSA undergraduate support mechanism (T34).

These programs are designed to support selected students at a variety of institutions, depending on the specific program.

Information about the specific programs are available in the applicable FOAs.

11.3.2.6 Citizenship

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Noncitizen nationals are individuals who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on their passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the recipient's responsibility to follow up and ensure that the individual received the I-551 prior to the 6-month expiration date.

A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271). Individuals with a Conditional Permanent Resident status may be supported on Kirschstein-NRSA training grants; however, as with all types of Permanent Resident status it is the recipient's responsibility to assure the individual remains eligible for NRSA support for the period of time of any appointment. Individuals with Asylum/Refugee status do not automatically hold a form of permanent residency status; they have the opportunity to apply for permanent residency status once they have been in the U.S. for a period of time. Therefore, individuals with Asylum/Refugee status may not be appointed to a Kirschstein-NRSA training grant until they have also secured permanent residency status. Individuals on temporary or student visas are not eligible for Kirschstein-NRSA support.

11.3.3 Application Requirements and Due Dates

11.3.3.1 Application

All applications for Kirschstein-NRSA institutional research training grants are submitted electronically through Grants.gov and use an application package that combines form components from the SF424 (R&R) application along with the PHS398 components. Application forms and instructions are provided as part of each FOA. Applicants should pay particular attention to the special instructions for institutional research training grants found in the SF424(R&R) Application Guide.

11.3.3.2 Due Dates

Several NIH ICs receive training grant applications three times each year; however, many ICs use only one or two receipt dates. Information on IC-specific receipt dates is available in the *NIH Guide for Grants and Contracts* in the NIH-wide T32 and T35 FOAs and FOAs issued by the individual NIH ICs or by contacting the appropriate NIH IC program official. For a list of the standard receipt dates and review cycle, see the https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm. (Also see http://researchtraining.nih.gov.)

Applicants are encouraged to contact the appropriate NIH staff before preparing and submitting an application. Applications requesting funding of $500,000 or more in direct costs for any year must generally

include a cover letter identifying the NIH staff member within the specific NIH IC who has agreed to accept assignment of the application. NIH ICs, however, may opt to forgo this requirement for certain types of grants, such as training grants; applicants should consult the Funding Opportunity Announcement for specific instruction and/or contact the NIH IC if there are questions about the applicability of this policy.

11.3.3.3 Special Program Considerations

The duration of training, the transition of trainees to individual support mechanisms, and their transition to the next career stage are important considerations in institutional training programs. Studies have shown that the length of the research training grant appointment of postdoctoral trainees with health-professional degrees strongly correlates to subsequent application for and success in receiving independent NIH research support. Therefore, Training PD/PIs should appoint only those individuals who are committed to a career in research and plan to remain on the training grant or in a non-Kirschstein-NRSA research experience for a minimum of 2 years in the aggregate. It also has been shown that transition to independent support is related to career success. Therefore, Training PD/PIs also should encourage and provide training in the skills necessary for postdoctoral trainees to apply for subsequent support through individual postdoctoral fellowships, mentored career development awards (K programs), or independent research project grants. When reviewing Kirschstein-NRSA institutional research training grant applications, peer reviewers will examine the training record to determine the average duration of training appointments for health-professional postdoctoral trainees and whether there is a history of transition to individual support mechanisms.

Studies also have shown that health professional trainees that train in combined programs with postdoctoral researchers with intensive research experience are more likely to apply for and receive research grant support. Programs located in clinical departments that focus on research training for individuals with the M.D. or other health-professional degrees should consider developing ties to basic science departments, or, if consistent with the goals of the program, modifying the program to include individuals with research doctorates. In these cases, applications should describe the basic science department's contribution to the research training experience and also indicate whether both health professional trainees and trainees with research doctorates will be included in the training program.

Training PD/PIs also must develop methods for ongoing evaluation of the quality and effectiveness of the training program. This should include plans to obtain feedback from current and former trainees to help identify weaknesses in the program and provide suggestions for program improvements as well as plans for assessing trainee's career development and progression, including publications, degree completion, and post-training positions. Evaluation results are to be included in competing continuation (renewal) applications and as part of the Final RPPR.

Within the framework of the program's longstanding commitment to excellence and projected need for investigators in particular areas of research, attention must be given to recruiting trainees from diverse backgrounds, including racial or ethnic groups underrepresented in the biomedical, behavioral and clinical sciences, individuals with disabilities, and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research. Institutions are encouraged to identify candidates who will enhance diversity on a national or institutional basis. NIH's requirements for diversity recruitment and retention are described below.

11.3.3.4 Recruitment Plan to Enhance Diversity

Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation–requires superior intellect, creativity and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remains a global leader in scientific

discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission.

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust.

Underrepresented Populations in the U.S. Biomedical, Clinical, Behavioral and Social Sciences Research Enterprise

In spite of tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. NIH encourages institutions to diversify their student and faculty populations to enhance the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral and social sciences, such as:

A. A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see data at http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27, and the report Women, Minorities, and Persons with Disabilities in Science and Engineering). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be demonstrated convincingly to be underrepresented by the recipient institution should be encouraged to participate in NIH programs to enhance diversity. For more information on racial and ethnic categories and definitions, see the OMB Revisions to the Standards for Classification of Federal Data on Race and Ethnicity

B. Individuals with disabilities, who are defined as those with a physical or mental impairment that substantially limits one or more major life activities, as described in the Americans with Disabilities Act of 1990, as amended. See NSF data at, https://www.nsf.gov/statistics/2017/nsf17310/static/data/tab7-5.pdf.

C. Individuals from disadvantaged backgrounds, defined as those who meet *two or more* of the following criteria:

1. Were or currently are homeless, as defined by the McKinney-Vento Homeless Assistance Act (Definition: https://nche.ed.gov/mckinney-vento/);
2. Were or currently are in the foster care system, as defined by the Administration for Children and Families (Definition: https://www.acf.hhs.gov/cb/focus-areas/foster-care);
3. Were eligible for the Federal Free and Reduced Lunch Program for two or more years (Definition: https://www.fns.usda.gov/school-meals/income-eligibility-guidelines);
4. Have / had no parents or legal guardians who completed a bachelor's degree (see https://nces.ed.gov/pubs2018/2018009.pdf);
5. Were or currently are eligible for Federal Pell grants (Definition: https://www2.ed.gov/programs/fpg/eligibility.html);
6. Received support from the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) as a parent or child (Definition: https://www.fns.usda.gov/wic/wic-eligibility-requirements).
7. Grew up in one of the following areas: a) a U.S. rural area, as designated by the Health Resources and Services Administration (HRSA) Rural Health Grants Eligibility Analyzer (https://data.hrsa.gov/tools/rural-health), or b) a Centers for Medicare and Medicaid Services-designated Low-Income and Health Professional Shortage Areas (qualifying zipcodes are included in the file). Only one of the two possibilities in #7 can be used as a criterion for the disadvantaged background definition.

Students from low socioeconomic (SES) status backgrounds have been shown to obtain bachelor's and advanced degrees at significantly lower rates than students from middle and high SES groups (see https://nces.ed.gov/programs/coe/indicator_tva.asp), and are subsequently less likely to be represented in biomedical research. For background see Department of Education data at, https://nces.ed.gov/; https://nces.ed.gov/programs/coe/indicator_tva.asp; https://www2.ed.gov-/rschstat/research/pubs/advancing-diversity-inclusion.pdf

D. Literature shows that women from the above backgrounds (categories A, B, and C) face particular challenges at the graduate level and beyond in scientific fields. (See, e.g., From NIH: A Systems Approach to Increasing the Diversity of Biomedical Research Workforce https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5008902/)

Women have been shown to be underrepresented in doctorate-granting research institutions at senior faculty levels in most biomedical-relevant disciplines, and may also be underrepresented at other faculty levels in some scientific disciplines (See data from the National Science Foundation National Center for Science and Engineering Statistics: Women, Minorities, and Persons with Disabilities in Science and Engineering, special report available at https://www.nsf.gov/statistics/2017/nsf17310, especially Table 9-23, describing science, engineering, and health doctorate holders employed in universities and 4-year colleges, by broad occupation, sex, years since doctorate,

and faculty rank).

Upon review of NSF data, and scientific discipline or field related data, NIH encourages institutions to consider women for faculty-level, diversity-targeted programs to address faculty recruitment, appointment, retention or advancement.

Training Program Requirements

NRSA training programs require all applicants to submit a recruitment plan to enhance diversity. New applications must include such a plan and may wish to include data in support of past accomplishments. Renewal applications also must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous the funding period. Information must be included on successful and unsuccessful recruitment strategies and how the proposed plan reflects the program's past experiences in recruiting individuals from underrepresented groups.

Applications without a recruitment plan to enhance diversity will be considered incomplete and will not be reviewed.

The review panel's evaluation will generally be included in an administrative note in the summary statement. If the recruitment plan to enhance diversity is judged to be unacceptable, funding will be withheld until a revised plan (and report) that addresses the deficiencies is received. Staff within the NIH IC, with guidance from its National Advisory Council or Board, will determine whether amended plans and reports submitted after the initial review are acceptable.

A detailed account of experiences in recruiting individuals from underrepresented groups during the previous budget period also must be provided in the non-competing progress report submitted as a prerequisite to receiving non-competing continuation support.

11.3.3.5 Training in the Responsible Conduct of Research

Every trainee supported by an NRSA training grant must receive instruction in the responsible conduct of research. All applications must include a plan to provide such instruction. The plan must address the five components listed below. Renewal (Type 2) applications must, in addition, describe changes in formal instruction over the past project period and plans for the future to address any weaknesses in the current instructional plan. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application. Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process. Plans and past record will be rated as acceptable or unacceptable. Applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan. For additional instructions, see the specific FOA.

1. ***Format.*** Discussion-based instruction in the responsible conduct of research is expected to remain a key feature of RCR training and to include substantive face-to-face interaction among participants and faculty. However, recognizing that advances in video conferencing now allow for effective "face-to-face" discussions to occur electronically, institutions may wish to consider incorporating video conferencing options into their RCR instruction, provided that those options are utilized in a way that fosters discussion, active learning, engagement, and interaction among the participants. At the same time, video conferencing should not be the sole means for meeting the requirement for RCR instruction, and a plan that employs only video conferencing will not be considered acceptable, except in special instances of short-term training programs, or unusual and well-justified circumstances

2. ***Subject Matter.*** Developments in the conduct of research and a growing understanding of the impact of the broader research environment have led to a recognition that additional topics merit inclusion in discussions of the responsible conduct of research, including:

a. conflict of interest – personal, professional, and financial – and conflict of commitment, in allocating time, effort, or other research resources

b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices

c. mentor/trainee responsibilities and relationships.

d. safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)

e. collaborative research including collaborations with industry and investigators and institutions in other countries

f. peer review, including the responsibility for maintaining confidentiality and security in peer review

g. data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks;

h. secure and ethical data use; data confidentiality, management, sharing, and ownership

i. research misconduct and policies for handling misconduct

j. responsible authorship and publication

k. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

3. ***Faculty Participation.*** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.

4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the trainees and the participating faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Existing policy and guidance call for RCR instruction to be undertaken at least once during each career stage, and at a frequency of no less than once every four years. As institutions consider how to optimize the timing and delivery of instruction in the responsible conduct of research, they are encouraged to bear in mind the value of ongoing and discipline-specific training as individuals progress in their research careers. For example, while broad-based instruction in the responsible conduct of research is often appropriate early in graduate school; a more tailored, discipline-specific approach may better fit the needs of advanced graduate students and those who have transitioned to postdoctoral status. If advanced students and postdoctorates have been exposed to the full range of topics traditionally included in RCR instruction early in their scientific training, it may make sense for their

ongoing and/or subsequent RCR training to focus on subjects most relevant to their fields, and institutions may wish to consider this approach, where applicable.

Information on the nature of the instruction in the responsible conduct of research and the extent of trainee and faculty participation also must be provided in the annual progress report submitted as a prerequisite to receiving non-competing continuation support.

11.3.4 Review

11.3.4.1 Overall

Each initial and competing continuation application will be evaluated for scientific merit by an NIH peer review group. Kirschstein-NRSA institutional research training grant applications also must be reviewed by the National Advisory Council or Board of the IC whose activities relate to the proposed research training.

11.3.4.2 Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the research training program to exert a sustained, powerful influence on the research field(s) involved. The scored review criteria and additional review criteria (as applicable for the research training program proposed) will be considered when determining the overall impact.

11.3.4.3 Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific merit.

- Training Program and Environment
- Training Program Director/Principal Investigator
- Preceptor/Mentors
- Trainees
- Training Record

The FOA should be consulted for additional information describing each of the scored review criteria. Individual Institutes and Centers may have additional specialized review criteria appropriate for their special initiatives and mission.

11.3.4.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards
- Training in Methods for Enhancing Reproducibility
- Resubmission Applications

- Renewal Applications
- Revision Applications

The FOA should be consulted for additional information describing each of the relevant addition review criteria.

11.3.4.5 Additional Review Considerations

As applicable for the training program proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing the overall impact score:

- Recruitment Plan to Enhance Diversity
- Training in the Responsible Conduct of Research
- Select Agents Research
- Budget and Period of Support

The FOA should be consulted for additional information describing each of the relevant addition review considerations.

11.3.4.6 National Advisory Council Review

Following initial peer review, applications undergo a second-level review by the appropriate NIH IC's National Advisory Council or Board. In addition to the assessment of the scientific and educational merit of the research training grant application, these advisory groups will consider the initial peer review group's comments on the plan for recruitment to enhance diversity and the plan for instruction in the responsible conduct of research.

11.3.5 Notification of Action

Shortly after the initial peer review meeting, the PD/PI will be sent an e-mail indicating that the SRG recommendation/impact score is available in the eRA Commons. The PD/PI is also notified via an e-mail when the summary statement is available in the eRA Commons. The PD/PI may be notified by the PO of the final review recommendation. Once all administrative and programmatic issues have been resolved, the NoA will be issued for applications selected for funding. Any questions concerning initial review recommendations and funding possibilities should be directed to the named PO, not to the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons.

11.3.6 Period of Support

11.3.6.1 Training Grants

Kirschstein-NRSA institutional research training grants may be made for competitive segments of up to 5 years and are renewable. Awards within an approved competitive segment normally are made in 12-month increments, referred to as budget periods; support for additional non-competitive years depends on satisfactory progress, submission of all required trainee-related documents, and availability of funds.

11.3.6.2 Trainees

Trainees under Kirschstein-NRSA institutional research training grants generally are appointed for full-time 12-month continuous periods. An appointment or reappointment period may begin any time during a particular budget period but may not begin before the budget period start date of the grant year. An appointment or reappointment may not exceed 12 months without prior approval by the NIH awarding

IC. All trainees are required to pursue their research training on a full-time basis. Full-time is generally defined as devoting at least 40 hours per week to the program or as specified by the recipient institution in accordance with its own policies. Unless the NIH awarding IC furnishes other instructions, the amount of the stipend, tuition, and fees for each full period of appointment must be obligated by the recipient from funds available when the individual begins training.

With the exception of specifically designated short-term research training positions, no trainee may be appointed under a regular Kirschstein-NRSA institutional research training grant for less than 9 months except with the prior written approval of the NIH awarding IC and then usually only to complete an ongoing program of training. An initial appointment of less than 9 months may be allowed as long as an assurance is included that the individual will be immediately reappointed in the subsequent year so that the cumulative continuous training period is at least 9 months.

Part-Time Training. While Kirschstein-NRSA trainees are required to pursue research training on a full-time basis, under certain circumstances, a written request may be submitted to the NIH awarding IC to change a trainee appointment to less than full time. All such requests must be signed by the trainee, the AOR and the training grant PD/PI. The request for part-time training must provide a justification of the need for a reduced level of effort and the expected duration of the period of part-time training. Such requests will be considered case-by-case and must be approved by the awarding IC before the applicable budget period. The circumstances requiring the part-time training might include medical conditions, disability, or personal or family situations such as a child or elder care. Part-time training will not be approved to accommodate use of other sources of funding, job opportunities, clinical practice, clinical training, or for other responsibilities associated with the trainee's position at the organization. In each case, the written request must be signed by an AOR and must include documentation supporting the need for part-time training. Countersignatures of the trainee and program director must be secured and retained by the recipient, but need not be submitted to NIH prior to submission to NIH. The written request also must include an estimate of the expected duration of the period of part-time training and assurances that the trainee intends to return to full-time training when that becomes possible and intends to complete the research training program.

The stipend may be prorated in the grant award during the period of any approved part-time training. Part-time training also may affect the rate of accrual or repayment of the service obligation for postdoctoral trainees. In no case will it be permissible for the trainee to be engaged in Kirschstein-NRSA-supported research for less than 50 percent effort. Individuals who must reduce their commitment to less than 50 percent effort must take a leave-of-absence from a Kirschstein-NRSA training grant.

11.3.6.3 Kirschstein-NRSA Limitations

No individual trainee may receive more than 5 years of aggregate Kirschstein-NRSA support at the predoctoral level and 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from Kirschstein-NRSA institutional research training grants and individual fellowships.

Any exception to the maximum period of support requires a waiver from the NIH awarding IC based on review of a justification from the individual and the recipient organization. The AOR must make the request in writing to the NIH awarding IC on behalf of the trainee. The endorsement of the trainee's PD/PI certifying the need for additional support is retained by the recipient institution. The request must specify the amount and length of additional support for which approval is sought.

Some generally recognized categories under which NIH may grant exceptions include the following:

- ***Physicians/Clinicians.*** Individuals requiring additional time to complete training, either as participants in a combined M.D./Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training, may anticipate favorable consideration of a request for waiver of the time limitation. This action is contingent upon an assurance of the trainee's good academic standing and justified need for the exception to this policy.
- ***Interruptions (Break in Service).*** Requests for additional time also will be considered if an event unavoidably has altered the planned course of the research training, if the interruption has significantly detracted from the nature or quality of the planned research training, and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation that prevents a trainee from effectively pursuing research training for a significant period of time. Requests for extension of support also will be considered if a short additional period would provide the trainee an opportunity to use an exceptional training resource directly related to the approved research training program.

Requests that arise from circumstances other than those described above will be considered only if they are accompanied by an exceptionally strong justification.

11.3.7 Initiation of Support

The NoA is issued to the recipient organization, generally for a budget period of 12 months. A trainee may be appointed any time during the budget period for an appointment period of 9 to 12 months, without prior approval by the NIH awarding IC. A trainee appointment may not begin before the budget period start date.

At the time of the initial appointment and subsequent reappointment of trainees, the Training PD/PI must submit a Statement of Appointment for each trainee to the NIH awarding IC. In addition, a signed Payback Agreement must be submitted for each postdoctoral trainee who is in their first 12 months of Kirschstein-NRSA postdoctoral support. See Reporting Requirements—Statement of Appointment (Form PHS 2271) and Reporting Requirements—Payback Agreement (Form PHS 6031) in this chapter for specific information on required forms. The Statement of Appointment includes biographical data on the trainee and the stipend level for the period of appointment. The stipend is paid by the recipient organization directly to the trainee.

11.3.8 Allowable and Unallowable Costs

Policies included in the applicable cost principles in 2 CFR Part 200, Subpart E and 45 CFR Part 75, Subpart E and the NIHGPS govern the expenditure of all training grant funds, unless otherwise indicated in the NoA.

11.3.8.1 Pre-Award Costs

While some pre-award costs are allowable to a training grant, recipients should note that stipends and tuition and fees may not be charged to a grant until a trainee has been officially appointed and the appropriate paperwork submitted to NIH. Therefore, these costs may not be charged as pre-award to an institutional training grant. There are rare occasions when costs associated with training related expenses and/or trainee travel may be allowable as pre-award costs. Recipient institutions should consult with the NIH awarding IC when considering a pre-award cost.

11.3.8.2 Stipends

Trainees generally are supported for 12-month full-time training appointments for which they receive a stipend as a subsistence allowance to help defray living expenses during the research training experience. The stipend is not "salary" and is not provided as a condition of employment with either the Federal government or the recipient organization. Stipends must be paid in accordance with established stipend levels. No departure from the standard stipend provided by NIH under the grant may be negotiated by the recipient organization with the trainee. NIH stipend amounts may be adjusted only at the time of appointment or reappointment. For appointments of less than 12 months, the stipend will be prorated.

Stipend levels are updated almost every fiscal year. When increases are approved, they are published in *NIH Guide for Grants and Contracts*. Current levels also are posted on NIH's Research Training and Career Development web page..

Stipend levels are as follows:

- ***Prebaccalaureate.*** One stipend level is provided for trainees.
- ***Predoctoral.*** One stipend level is used for all predoctoral trainees, regardless of the level of experience.
- ***Postdoctoral.*** The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience at the time of appointment. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the trainee must be paid at that level for the entire period of appointment. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.

11.3.8.3 Trainee Tuition and Fees

Tuition and fees are allowable trainee costs only if such charges are applied consistently to all individuals in a similar training status at the organization, without regard to their source of support.

Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program and requires NIH awarding IC prior approval.

Tuition and fees are provided under the following policy:

- ***For Predoctoral Trainees.*** An amount equal to 60% of the level requested by the sponsoring institution, up to $16,000 per year, will be provided. If the program supports formally combined dual-degree training (e.g., M.D.-Ph.D, D.D.S.-Ph.D.), the amount provided will be up to $21,000 per year.
- ***For Postdoctoral Trainees.*** An amount equal to 60% of the level requested by the applicant institution, up to $4,500 per year, will be provided. If the program supports postdoctoral individuals in formal degree-granting training, the amount provided will be up to $16,000 per year.

Tuition and fees are awarded as a lump sum that can be allocated (without the prior approval of the NIH awarding IC) based on recipient needs.

11.3.8.4 Training-Related Expenses

Funds are provided to defray costs such as staff salaries, consultant costs, equipment, research supplies, staff travel, trainee health insurance (self-only or family as applicable), and other expenses directly related to the training program. Funds are requested and awarded as a lump sum on the basis of the

predetermined amount per predoctoral and postdoctoral trainee approved for support. Levels are published in the *NIH Guide for Grants and Contracts*. Interested applicants should consult the program announcement regarding the specific level for programs such as the short-term training program or the MARC program. Many of the costs allowable under Training-Related Expenses may cover global costs for an institutional training program where the Kirschstein-NRSA support covers only some of the participating trainees. For these types of global costs, institutions should allocate the appropriate portion of such costs to the training grant. Institutions are reminded that this budget category is a finite amount of money available to cover a variety of allowable costs. Institutions should be particularly mindful to apply core cost principles of allocation and consistent treatment.

Health Insurance. Health Insurance (self-only or family) are allowable trainee related expenses only if such charges are applied consistently to all individuals in a similar training status at the organization, without regard to their source of support. Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy. Health insurance is awarded as part of the Training Related Expenses category.

Medical Liability and Other Special Insurance. Medical liability (malpractice) insurance or other special insurance is an allowable cost to NRSA grants only if nature of the research training requires such special insurance. For instance, medical liability would be allowable if the research training experience involves direct contact with patients or human subjects. In all cases, for the cost to be charged to the NRSA grant, it must be consistently required for all in a similar training status, regardless of the source of support. Special insurances that are routinely offered as optional employee benefits (such as disability insurance, life insurance, or workman's compensation insurance), are not normally allowable charges (see separate section on Employee Benefits) unless the nature of the research training requires such special insurance.

Staff Salaries. Institutions are reminded that applicable cost principles apply. Training programs may qualify as a "major project" where administrative salaries are allowable as a training-related expense.

Speaker Fees. When speakers are part of program required for NSRA-supported trainees, a portion of such a cost could be charged as Training-related expenses.

Meals. As stated in IIA, the cost of meals may be allowable if they are provided in conjunction with a meeting considered an ancillary activity to the training grant. A portion of such a cost could be charged as Training-related expenses. See Cost Considerations—The Cost Principles in IIA for specific guidance on the need institutional policies on consistent treatment and reasonableness.

Extraordinary Costs. Under exceptional circumstances, which can include accommodating the disabilities of a trainee, it is possible to request organizational costs above the standard level. Requests for additional costs must be explained in detail and justified in the application. Consultation with NIH program staff in advance of such requests is strongly advised.

11.3.8.5 Trainee Travel Costs

If requested by the recipient, the NIH awarding IC may provide grant funds to cover the costs of trainee travel, including attendance at scientific meetings, which the organization determines is necessary to the individual's training. Trainees must be appointed to the training grants at time of the actual travel for this to be an allowable cost. Funds may not be expended to cover the costs of travel between the trainee's place of residence and the training institution, except that the recipient organization may authorize a one-way travel allowance in an individual case of extreme hardship.

In addition, support for travel to a research training experience away from the recipient organization may be permitted. Research training experiences away from the parent organization must be justified on the basis of the type of opportunities for training available, the opportunities offered that are different from

those at the parent organization, and the relationship of the proposed experience to the trainee's career stage and career goals. This type of research training requires prior approval of the NIH awarding IC. Letters requesting such training may be submitted to the NIH awarding IC at any time during the appointment period.

11.3.8.6 Short-Term Training Costs

The recipient may receive up to one-twelfth of the annual amount designated for training-related expenses each month to offset the costs of tuition, fees, travel, supplies, and other expenses for each short-term, health-professional research training position.

11.3.8.7 Employee Benefits

Because Kirschstein-NRSA awards are not provided as a condition of employment with either the Federal government or the recipient, it is inappropriate and unallowable for organizations to seek funds, or to charge Kirschstein-NRSA institutional research training grants, for costs that normally would be associated with employee benefits (for example, FICA, workers compensation, life insurance, union dues, and unemployment insurance). Concerning union dues or other similar costs otherwise paid personally by the trainee, if a trainee requests the institution deduct such a cost from the stipend amount, the institution can provide the trainee such a service. However, in no case can such a deduction from the stipend be made automatically without the approval of the trainee and institution.

11.3.8.8 Facilities and Administrative Costs

Recipients, other than State, local, or Indian tribes (or ''federally recognized Indian tribes"), will receive F&A costs at 8 percent of modified total direct costs (exclusive of tuition and fees, childcare costs, consortiums in excess of $25, 000, and expenditures for equipment) rather than on the basis of a negotiated rate agreement. State, local, and Indian tribe (or ''federally recognized Indian tribes") are eligible for full F&A cost reimbursement. For this policy, State universities or hospitals are not considered governmental agencies.

11.3.9 Rebudgeting of Funds

Funds may be rebudgeted only as follows:

- ***Trainee-Related Expenses.*** Rebudgeting of funds awarded in a lump sum for trainee-related expenses does not require NIH awarding IC prior approval.
- ***Trainee Costs.*** For rebudgeting purposes, trainee costs include funds awarded in the stipends or tuition/fees budget categories. These costs may not be used for other purposes except under unusual circumstances and then only with the prior approval of the NIH awarding IC. Unless otherwise restricted, rebudgeting into or within the stipends and tuition/fees is allowable without prior approval of the NIH awarding IC.
- ***Trainee Travel.*** For rebudgeting purposes, trainee travel is not considered a trainee cost and, therefore, may be rebudgeted into any other budget category without prior approval of the NIH awarding IC.

11.3.10 Stipend Supplementation, Compensation, and Other Income

11.3.10.1 Stipend Supplementation

Recipients may supplement stipends from non-Federal funds provided the supplementation is without any additional obligation for the trainee. An organization can determine what amount of stipend

supplementation, if any, will be provided according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar training status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. An individual may use Federal educational loan funds or VA benefits when permitted by those programs as described in Educational Loans or GI Bill below. Under no circumstances may PHS funds be used for supplementation.

11.3.10.2 Compensation

NIH recognizes that student or postdoctoral trainees may seek part-time employment coincidental to their training program to further offset their expenses. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part time research, teaching, or clinical employment, so long as those activities do not interfere with, or lengthen, the duration of their NRSA training. Funds characterized as compensation may be paid to trainees only when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions of the compensation of students as detailed in Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Fringe Benefits / IHE Tuition/Tuition Remission in IIA. In addition, compensation must be in accordance with organizational policies consistently applied to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation (salary, fringe benefits, and/or tuition remission) for services rendered, such as teaching, laboratory assistance, or clinical duties are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. However, NIH expects that compensation from research grants will be for limited part-time employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant that supports the same research that is part of the trainee's planned training experience as approved in the Kirschstein-NRSA institutional research training grant application.

Stipend Supplementation & Compensation. Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the trainee's approved Kirschstein-NRSA training program. Training PD/PIs must approve all instances of employment on research grants to verify that the circumstances will not detract from or prolong the approved training program.

11.3.10.3 Other Income: Concurrent Benefits

An individual may not receive support under a Kirschstein-NRSA institutional research training grant concurrently with another federally sponsored fellowship or similar Federal or non-Federal award that provides a stipend or otherwise duplicates provisions of the Kirschstein-NRSA award.

11.3.10.4 Other Income: Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the VA (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation. In the case of the MARC-U*STAR program, funds from a Pell grant may be accepted as well.

11.3.10.5 Other Income: NIH Loan Repayment Program

Postdoctoral trainees also may be eligible to participate in the NIH Loan Repayment Program.

11.3.10.6 Taxability of Stipends

Section 117 of the Internal Revenue Code (26 U.S.C. 117) applies to the tax treatment of scholarships and fellowships. Degree candidates may exclude from gross income (for tax purposes) any amount used

for qualified tuition and related expenses, such as fees, books, supplies, and equipment, required for courses of instruction at a qualified educational organization. Nondegree candidates are required to report as gross income any monies paid on their behalf for stipends or any course tuition and fees required for attendance.

The IRS and Treasury Department released regulations in January 2005 (Revenue Procedures 2005-11) clarifying the student exception to the FICA (Social Security and Medicare) taxes for students employed by a school, college, or university where the student is pursuing a course of study. NIH's understanding is that these final regulations do **not** apply to or impact Kirschstein-NRSA programs or awards.

The taxability of stipends in no way alters the relationship between Kirschstein-NRSA trainees and recipient organizations. Kirschstein-NRSA stipends are not considered salaries. In addition, trainees supported under Kirschstein-NRSA institutional research training grants are not considered to be in an employee-employer relationship with NIH or the recipient organization solely as a result of the Kirschstein-NRSA support. Interpretation and implementation of the tax laws are the domain of the IRS and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

11.3.10.7 Form 1099

Although stipends are not considered salaries, the funds are subject to Federal and, sometimes, State taxes. The recipient organization may report such funds on IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the recipient organization will be responsible for annually preparing and issuing the IRS Form 1099 for trainees. Recipient organizations are not required to issue the Form 1099, but it is a useful form of documentation of funding received and it serves as a reminder to the trainee that some tax liability may exist. Even if the recipient organization does not issue the Form 1099, trainees are required to report Kirschstein-NRSA stipends as income.

11.3.11 Carryover Authority

NIH Standard Terms of Award apply to Kirschstein-NRSA institutional research training grants; however, in most cases, recipients must obtain awarding IC prior approval to carry over funds. Some NIH awarding ICs have also waived this prior approval requirement for training grants. The NoA for a Kirschstein-NRSA institutional research training grant will specify whether or not the recipient must obtain the prior approval of the awarding IC to carry over funds.

11.3.12 Program Income

Applicants for NIH research grants, including Kirschstein-NRSA institutional research training grants, are required to include in their grant applications an estimate of the amount and source of program income expected to be generated as a result of the project for which support is being sought. See Administrative Requirements—Management Systems and Procedures—Program Income in IIA for policies that govern the disposition and reporting of program income.

11.3.13 Reporting Requirements

The submission of the forms described in this subsection is critical to establishing the payment of stipends and other costs and determining possible payback service. Failure to submit the required forms in a timely manner may result in an expenditure disallowance or a delay in any continuation funding. All of these forms are available in PDF-fillable and MS Word formats.

11.3.13.1 Statement of Appointment (Form PHS 2271)

The recipient must submit a PHS 2271 to the NIH awarding IC before or at the start of each trainee's appointment or reappointment. No 2271s can be submitted until after the NoA for the respective budget period has been issued. Recipients are required to submit the PHS 2271 data electronically using the eRA Commons xTrain application. See xTrain for more information.

The requirement for ORCID identifiers is incorporated into the appointment process for trainees, scholars, and participants supported by institutional research training, career development, and research education awards that require appointments through the xTrain system, including the following: T03, T15, T32, T34, T35, T37, T42, T90/R90, TL1, TL4, TU2, K12/KL2, R25, R38, RL5, and RL9.

At the time of appointment, the xTrain system will check whether appointees have ORCID iDs and appointments will be not be accepted for agency review unless an ORCID iD is linked to the individual's eRA Commons Personal Profile.

No stipend or other allowance may be paid until the appointment form has been submitted. If the support covers the individual's initial 12 months of postdoctoral support, a signed Payback Agreement also must be submitted. The information on the Statement of Appointment (and the Termination Notice as discussed below) is the basis for determining the length or amount of an individual's payback requirement. The PD/PI and the organizations' financial officials should coordinate the information reported on the Statement of Appointment. It should be treated as a financial document for obligating funds (stipends), which later are reflected on the Termination Notice and as part of the total costs in the FFR.

Interim Revisions. Any changes or corrections involving a trainee appointment under a Kirschstein-NRSA institutional research training grant, such as name, permanent mailing address, period of training, or stipend support, must be reported by the Training PD/PI to the NIH awarding IC on an amended PHS 2271 at the time of the change, and be submitted through xTrain.

Consecutive Support. If a trainee switches from one Kirschstein-NRSA mechanism to another (e.g., from an individual fellowship to a training grant) or from one NIH awarding IC to another, the requirement for payback service incurred is deferred until the total period of Kirschstein-NRSA support is completed. All Statement of Appointment forms are reviewed to determine if previous Kirschstein-NRSA support has been provided.

11.3.13.2 Payback Agreement (Form PHS 6031)

A Payback Agreement that covers the initial 12 months of Kirschstein-NRSA postdoctoral support must be signed by each postdoctoral trainee. If the individual has already received 12 months of postdoctoral support under any Kirschstein-NRSA training grant or fellowship award, this form is not required. For details on Kirschstein-NRSA payback, see Payback Requirements in this chapter.

No Payback Agreement is required for predoctoral or prebaccalaureate trainees.

11.3.13.3 Termination Notice (Form PHS 416-7)

The Termination Notice (along with the PHS 2271 Statement of Appointment form) is the basis for validating the total period of Kirschstein-NRSA support and establishing the amount of payback obligation, if any, for each Kirschstein-NRSA trainee. The PD/PI is responsible for submitting a Termination Notice for each trainee within 30 days of the end of the total period of support even if the trainee is not available for signature. In most cases, the information on the form must be verified by the program director and an institutional business official, however, in cases where the program director is not available to sign the Notice within the required timeframe, the form may be verified by the institutional business official alone. The lack of timely and accurate information on this form could adversely affect data collected

associated with aggregate NRSA support and the payback process. Recipients are required to submit the PHS 416-7 data electronically using the xTrain application.

See xTrain for more information.

No Termination Notice is required for prebaccalaureate (T34) trainees.

11.3.13.4 Research Performance Progress Reports

RPPRs must be submitted for non-competing continuation support in accordance with the RPPR instructions. Report forms and instructions are available from the NIH web site. Guidance for training grants can be found in section 7.4 of the RPPR Instructions. Following completion or termination of a project period, the recipient must submit a Final RPPR to the NIH awarding IC within 120 days after the end of grant support.

The IDP provision described in Non-Competing Continuation Progress Reports applies to all trainees reported on a Statement of Appointment Form (PHS2271). This information should be provided using the instructions in Non-Competing Continuation Progress Reports.

11.3.13.5 Federal Financial Report (FFR)

An annual FFR is required for all Kirschstein-NRSA institutional research training grant awards no later than 90 days after the end of the calendar quarter in which the budget period ended. This report will document the financial status of the grant according to the official accounting records of the recipient organization. Trainee stipends and tuition are obligated for the full 12-month appointment from the budget period in which the appointment is initiated. Portions of stipends, tuition, and applicable F&A that extend beyond the budget period are reported as unliquidated obligations. The same principal may apply to trainee health insurance when an institution cannot truly obligate the full amount of health insurance at the start of the appointment.

If the report covers the final budget period of the project period, it must have no unliquidated obligations, must indicate the exact balance of unobligated funds, and is due within 120 days of the period of performance end date (see Administrative Requirements—Monitoring—Reporting—Financial Reports and Administrative Requirements—Closeout—Final Reports in IIA).

11.3.14 Closeout

The Closeout requirements included in IIA apply (see Administrative Requirements—Closeout—Final Reports). In addition, Termination Notices for all trainees are required.

11.3.15 Changes in the Project

Changes in the program objectives as they relate to the area of research training for which the grant was approved require prior approval of the NIH awarding IC.

If the PD/PI is expected to be absent more than 3 months, plans for the conduct of the program during their absence must be approved in writing by the NIH awarding IC. Any proposed change of PD/PI must be requested by the recipient organization and be approved in writing by the NIH awarding IC following review of the nominee's qualifications and re-evaluation of the project in light of the proposed change.

Kirschstein-NRSA institutional research training grants may not be transferred from one domestic organization to another except under the most unusual circumstances. Such a change generally will be approved by the NIH awarding IC only if all of the major benefits attributable to the original grant can be transferred and there is no negative impact on trainees active in the program.

11.3.16 Other Terms and Conditions

11.3.16.1 Leave

Note: The leave durations stated below apply to full-time trainees. Short-term trainee leave must be proportionally adjusted based depending on the duration of appointment.

In general, trainees may receive stipends during the normal periods of vacation and holidays observed by individuals in comparable training positions at the sponsoring institution. For the purpose of these awards, however, the period between the spring and fall semesters is considered to be an active time of research and research training and is not considered to be a vacation or holiday. Trainees may receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for the medical conditions related to pregnancy and childbirth. Trainees may receive stipends for up to *60 calendar days (equivalent to 8 work weeks)* of parental leave per year for the adoption or the birth of each child. Either parent is eligible for parental leave. Kirschstein-NRSA trainees and fellows must provide advanced notification to the recipient institution prior to taking parental leave. Notification of supervisors and others about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds. A period of terminal leave is not permitted, and payment may not be made from traineeship funds for leave not taken. Trainees requiring periods of time away from their research training experience longer than specified here, i.e., more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding component for an unpaid leave of absence. Approval for a leave of absence must be requested in advance by an AOR on behalf of the trainee. Trainees supported by academic institutions should refer to the NIH Institutional NRSA training grant guidelines in the NIH Grants Policy Statement for further guidance regarding vacations and requested leave.

Vacations and Holidays. Trainees may receive the same vacations and holidays available to individuals in comparable training positions at the recipient organization. Trainees will continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters generally is considered an active part of the training period and is not considered to be a vacation or holiday.

Sick Leave and Other Leave. Trainees may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for the medical conditions related to pregnancy and childbirth.

Parental Leave. Trainees may receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of each child. Either parent is eligible for parental leave. Kirschstein-NRSA trainees and fellows must provide advanced notification to the recipient institution prior to taking parental leave. Notification of supervisors and others about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds.

Terminal Leave. A period of terminal leave is not permitted, and payment may not be made from grant funds for leave not taken.

Unpaid Leave. Individuals requiring extended periods of time away from their research training experience, that is, more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding IC for an unpaid leave of absence. A request letter must be submitted by the AOR, signed by the trainee as well as the training grant PD/PI.

During a leave of absence, documentation to suspend the period of appointment must be completed by submitting an amended Statement of Appointment and a Termination Notice. These forms should be submitted to the NIH awarding IC at the beginning of the leave. Upon resumption of Kirschstein-NRSA support, the reappointment must be documented on another Statement of Appointment form.

11.3.16.2 Termination

NIH may terminate a Kirschstein-NRSA institutional research training grant before its normal completion date if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which the award was made. If an award is terminated, NIH will notify the recipient organization in writing of this determination, the reasons for the determination, the effective date, and the right to appeal the decision. NIH also may terminate an award at the request of the recipient.

An organization that wants to terminate a training grant before the scheduled termination date must notify the NIH awarding IC immediately. In such cases, NIH will issue a revised NoA to specify the changed period of support and to show prorated trainee stipends, depending on the amount of time spent in training.

11.3.16.3 Publications and Sharing of Research Results

NIH supports the practical application and sharing of outcomes of funded research. Therefore, PD/PIs and trainees should make the results and accomplishments of their Kirschstein-NRSA institutional training grant activities available to the research community and to the public at large. The recipient organization should assist trainees in these activities, including further development of discoveries and inventions for furthering research and benefiting the public. No restrictions should be placed on the publication of results.

Trainees are encouraged to submit reports of their findings for publication to the journals of their choice. Responsibility for direction of the project should not be ascribed to NIH. However, NIH IC support must be acknowledged by a footnote in language similar to the following: “This investigation was supported by the National Institutes of Health under Ruth L. Kirschstein National Research Service Award (number) from the (name of NIH IC).” In addition, Federal funding must be acknowledged as provided in Appropriation Mandates—Acknowledgment of Federal Funding in IIA.

The Public Access Policy requirements described in Administrative Requirements—Availability of Research Results—NIH Public Access Policy in IIA apply to articles that are authored or co-authored by NRSA trainees and arose from NIH Support. Information on trainee publications is included as part of the annual progress report.

11.3.16.4 Copyright

Except as otherwise provided in the NoA, when a publication or similar copyrightable material is developed from work supported by NIH, the author is free to arrange for copyright without the approval of the NIH awarding IC. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce, translate, publish, and use and dispose of such materials, and to authorize others to do so for Federal government purposes.

11.3.16.5 Inventions and Patents

All Kirschstein-NRSA institutional research training grants and other funding agreements awarded primarily for educational purposes are not subject to invention reporting requirements nor does NIH have any rights to inventions under those grants and agreements (as specified in 2 CFR 200.315 and 45 CFR Part 75.322 and in 37 CFR 401.1(b)).

11.3.16.6 Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award may not be retained by the trainee. Such fees must be assigned to the recipient organization for disposition in accordance with NIH policy on program income (see Administrative Requirements—Management Systems and Procedures—Program Income in IIA). The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations. If permitted by organizational policy, these fees may be retained by the trainee.

11.3.16.7 Public Policy Requirements and Objectives

All Public Policy Requirements, Objectives, and Other Appropriation Mandates discussed in IIA apply to Kirschstein-NRSA Institutional programs when appropriate. Applicants must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements and inclusion policies for women, minorities and individuals across the lifespan; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant or synthetic nucleic acid. See IIA for a complete list of applicable requirements.

Additional information and any application requirements can be found in the SF424 (R&R), Section 8. Supplemental Instructions for Preparing Institutional Ruth L. Kirschstein-NRSA Applications.

Information provided below is in addition to that provided in IIA where unique circumstances might exist for institutional training programs.

11.3.16.7.1 Human Subjects

Indefinite Involvement. If the applicant organization has an approved FWA or other applicable assurance on file with OHRP but, at the time of application, plans for the involvement of human subjects are indefinite, the assurance number should be provided in the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

In many instances, trainees supported by Kirschstein-NRSA institutional research training grants will be participating in research supported by research project grants for which the IRB review is already completed or an exemption is already designated. This review or exemption designation is sufficient, provided the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation. The recipient institution must ensure that trainees have received the proper training/education in human subjects research.

11.3.16.7.2 Vertebrate Animals

Indefinite Involvement. If the applicant organization has an approved Animal Welfare Assurance on file with OLAW but, at the time of application, its plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, the organization should indicate "Yes," to the involvement of Vertebrate Animals and include the Animal Welfare Assurance number. If an award is made, vertebrate animals may not be involved until verification of the IACUC approval date has been submitted to the NIH awarding IC.

In many instances, trainees supported by institutional research training grants will be participating in research supported by research project grants for which the IACUC review already is completed. This review is sufficient, provided the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC review dates. The institution

must ensure that trainees are enrolled in the institution's animal welfare training and occupational health and safety programs for personnel who have contact with animals, as appropriate. It is also the institution's responsibility to ensure that trainees are properly supervised when working with live vertebrate animals.

If the applicant organization does not have an approved Animal Welfare Assurance on file with OLAW or for additional information on vertebrate animals, refer to the Application Guide or contact OLAW (see Part III).

11.4 PAYBACK REQUIREMENTS

11.4.1 General

The Kirschstein-NRSA legislation requires some recipients of support (post-doctoral fellows and trainees) to pay back the Federal government by engaging in health-related research, health-related research training or health-related teaching (or any combination thereof). See Payback—Service Payback—Definitions in this subsection for complete coverage of requirements.

11.4.2 Implementation

The incurrence of a payback obligation for an NRSA recipient is solely dependent upon when NRSA support was received. This section reflects current Payback requirements for individuals.

Predoctoral Recipients. For predoctoral trainees no payback obligation is incurred. Thus a Payback Agreement Form (PHS 6031) is not required.

Postdoctoral Recipients. For individuals receiving postdoctoral support under individual fellowships or institutional research training grants, a payback obligation is incurred for the first 12 months of Kirschstein-NRSA support. However, the 13th and subsequent months of postdoctoral NRSA supported research training serves to pay back this obligation month by month. A Payback Agreement (PHS 6031) is required but only for the initial 12-month postdoctoral support period.

Short-Term Training. Any individual receiving support for predoctoral short-term training does not incur a payback obligation; however, postdoctoral short-term training does incur a payback obligation. Support for short-term training accrues, along with any subsequent NRSA postdoctoral support, until the first 12 months is established. At that point, the 13th and subsequent months of support serve to offset the obligation month by month. If subsequent postdoctoral support is not received, the individual has an obligation to pay back in the traditional manner.

11.4.3 Payback

Once a Termination Notice has been submitted and accepted, the NIH awarding IC determines if a payback obligation exists. When a trainee or fellow must pay back, the Termination Notice and related documents are forwarded to the NIH Kirschstein-NRSA Payback Service Center (PSC). PSC personnel are NIH's experts in Kirschstein-NRSA payback requirements. The PSC administers the payback activities of all NIH ICs. The authorities related to payback normally delegated to the IC are delegated to the Chief, Kirschstein-NRSA PSC. The PSC retains all records until an obligation is satisfied, and then transfers closed records to the Federal Records Center.

Most Kirschstein-NRSA recipients eventually fulfill their payback obligation by engaging in activities that are determined to be acceptable service. Some recipients fulfill their obligation via financial payback. On rare occasions, the payback obligation is waived.

As indicated in Payback Reporting Requirements—Implementation in this subsection, the amount of a payback obligation incurred is solely dependent on the total period of support and the laws in effect when the Kirschstein-NRSA support was received.

11.4.3.1 Service Payback

11.4.3.1.1 Definitions

For fulfilling the Kirschstein-NRSA service payback obligation, the following definitions apply:

- ***Research.*** Research is defined as an activity that involves designing experiments, developing protocols, and collecting and interpreting data. In addition, review of original research or administration of original research that includes providing scientific direction and guidance to research may be acceptable if a doctoral degree and relevant research experience is required for individuals filling such positions. Such research can be conducted in an academic, government, commercial, or other environment in either a foreign or domestic setting. In addition, when consistent with the cumulative amount, type, and frequency of research or research training experiences, functions that involve analytic or other technical activities conducted in direct support of research, as defined above, will also satisfy the service payback obligation.
- ***Teaching.*** Teaching is an instructional activity that takes place in an organized educational or other instructional environment. Activities classified as teaching are generally carried out in a formal didactic setting, but other activities will be considered if they are consistent with the certifying institution's policy on the definition of teaching responsibilities. Such teaching can be conducted at universities, professional schools, research institutes, teaching hospitals, primary schools, secondary schools, or colleges. When calculating hours of teaching per week, it is permissible to include 3 hours of preparation time for each hour of direct instruction. Acceptable teaching activities must have a biomedical or health-related relevance.
- ***Health-Related .*** "Health-related" means related to the description, diagnosis, prevention, or treatment of disease. Fields other than those usually considered to be directly related to human disease, such as agriculture, environmental sciences, biotechnology, and bioengineering, also will be considered health-related.

11.4.3.1.2 Time Commitment

All acceptable activities must be undertaken for periods that average at least 20 hours per week. Total employment in such activities averaging less than 20 hours per week cannot be counted toward fulfilling the obligation except in cases of disability or other pressing personal or family circumstances, such as childcare or elder care responsibilities. It is not permissible for individuals otherwise engaged in full-time employment to engage in service payback activities at effort levels below 20 hours per week.

If less than 20 hours commitment per week is permitted, the total period of service obligation will be prorated. For example, an individual who owes 12 months of service and can devote only 10 hours per week to service payback activities due to a disability will be required to engage in such service for 24 months. These exceptions are rare and must receive prior approval from the PSC.

11.4.3.1.3 Initiation of Payback Service

Service payback obligations for postdoctoral recipients may be discharged by

- receiving an equal number of months of postdoctoral Kirschstein-NRSA support beginning in the 13th month of such postdoctoral Kirschstein-NRSA support, or

- engaging in an equal number of months of health-related research, health-related research training, or health-related teaching (or any combination thereof) that averages more than 20 hours per week.

11.4.3.1.4 Source of Funding

There is no restriction on the source of funds supporting an individual's service payback activity. An individual could be supported by a PHS grant or any non-Kirschstein-NRSA Federal or non-Federal source. Unpaid service also is permitted.

11.4.3.1.5 Timing of Service Obligation

An individual must begin to undertake the payback service requirement within 2 years after the termination date of the individual's Kirschstein-NRSA support unless an extension of time to begin payback has been approved by the PSC (see Payback—Extensions of Payback—Extensions of the 2-Year Period to Initiate Payback below).

11.4.3.2 Financial Payback

11.4.3.2.1 Policy and Principal Calculation

If an individual does not perform payback service, the Federal government shall be entitled to recover certain costs. The amount the United States is entitled to recover depends on when support was received. Calculation formulas take into account the total amount paid the individual (see Interest and Interest Rate Calculation below), less any obligation already fulfilled through service or legislative allowance when applicable. The total paid an individual under an institutional research training grant or individual fellowship award at a domestic, non-Federal sponsoring institution is considered to be the stipend only. The total paid an individual under a fellowship award at a foreign sponsoring institution includes the payment for the round-trip travel costs. The total paid an individual under a fellowship award at a Federal sponsoring institution includes any money expended from the institutional allowance provided for such purposes as health insurance, travel, tuition, and fees.

11.4.3.2.2 Interest and Interest Rate Calculation

NIH computes interest on the principal amount beginning on the date the United States became entitled to recover stipends. The interest rate is the rate fixed by the Secretary of the Treasury after considering prevailing consumer rates of interest. Accordingly, interest may accrue on any Kirschstein-NRSA obligation if the 2-year grace period has passed, if deferment has expired, or if service has terminated before completion of the payback obligation. The Department of the Treasury certifies Kirschstein-NRSA interest rates quarterly. Interest is computed on a 360 day-a-year basis and is applied through the date of receipt. Any outstanding amount will continue to bear interest at the initial rate set by the Secretary of the Treasury until financial payback is complete.

The date that sets the applicable rate of interest depends on the type of Kirschstein-NRSA account received for collection. If financial payback is voluntary, the signature date of the notification of voluntary payback is the date that determines the interest rate as well as the initiation of the 3-year repayment period. If financial payback is involuntary, the date that sets the interest rate and the 3-year repayment period is the date of expiration of the 2-year period following the completion date or termination of Kirschstein-NRSA support. For example, if during June 2021, OFM received an account reflecting January 31, 2019, as the termination date of NRSA support, the Federal government, lacking any documentation to the contrary, becomes entitled to financial payback effective February 1, 2019.

The rate of interest applicable is determined based on the February 1, 2019, date, and the total NRSA obligation is required to be fulfilled by January 31, 2022.

The amount to be recovered financially, as determined from the Termination Notice plus applicable interest, shall be paid to the United States within the 3-year period following such date.

11.4.3.3 Extensions of Payback

The authorizing legislation and the implementing regulations (42 CFR Part 66) permit exceptions to certain requirements under the Act.

11.4.3.3.1 Extensions of the 2-Year Period to Initiate Payback

An extension of the 2-year period to initiate payback may be requested in the Annual Payback Activities Certification form. Indication of valid plans to initiate payback soon after the 2-year grace period may be good reason to grant an extension.

11.4.3.3.2 Basis for Extensions or Break in Service

The PSC may extend the period for undertaking payback service or permit breaks in continuous service. These determinations are based on the following criteria:

- An extension or break in service is necessary so the individual may complete their non-health related research or clinical training.
- An extension or break in service is necessary so the individual may participate in the NIH Loan Repayment Program.
- The individual is unable to complete the requirements within the specified period because of a temporary disability.
- Completion by the individual of the requirement within the specified period would involve substantial hardship to the individual, and failure to extend the period would be against equity and good conscience.

Reasons for an extension or break in service include, for example, completing residency training where clinical teaching or research are not an integral part of the training, or seeking employment that would fulfill the payback requirements.

Participation in LRP will result in an automatic deferral of the NRSA obligation because concurrent payback under both LRP and NRSA is not permissible. Payback service cannot begin until after LRP has ended.

11.4.3.4 Waiver

11.4.3.4.1 Policy

The authorizing legislation and the implementing regulation (42 CFR Part 66) permit exceptions to certain requirements under the Act. NIH may waive, in whole or in part, the payback obligation, upon determination that compliance by the individual is impossible or would involve substantial hardship, and enforcement of the individual's obligation would be against equity and good conscience.

11.4.3.4.2 Waiver Criteria

Requests for waivers should be made in writing to the PSC and should include an explanation of the need for the waiver according to the following criteria:

- Compliance by an individual will be deemed impossible if the individual is permanently, and totally disabled.
- In determining whether compliance would involve substantial hardship to the individual and would be inequitable, the PSC will consider the individual's
    - financial resources and obligations at the time of request for a waiver and
    - estimated future financial resources and obligations.
- In rare cases, the following also may be considered:
    - Reasons for the individual's failure to complete the requirements within the prescribed period, such as personal problems;
    - Extent to which the individual has engaged in payback activities;
    - Sufficiency of training to qualify the individual to perform such activities;
    - Lack of employment opportunities appropriate to the individual's education and training;
    - Any other extenuating circumstances.

Any obligation of any individual toward payback will be canceled upon death of the individual.

11.4.4 Certification of Payback Activities

11.4.4.1 Annual Payback Activities Certification (Form PHS 6031-1)

11.4.4.2 Annual Certification

Payback service is certified through the use of the Kirschstein-NRSA APAC (PHS 6031-1). Individuals with an outstanding payback obligation must complete an APAC annually until their payback obligation is fulfilled.

If an individual has a payback obligation, an APAC is sent by the PSC approximately one year after the completion of Kirschstein-NRSA support. Payback service may be initiated within the first 12 months of termination even though trainees and fellows have up to 24 months to initiate payback. There is no penalty to those individuals who do not initiate payback within the first 12 months; however, it is critical that they complete an APAC form to ensure contact is maintained and addresses are current.

The individual will report on the APAC the activity in which they were engaged for the preceding 12 months, within the specified reporting period. These forms are to be returned within 30 days of the reporting period end date to the address specified on the mailing label included with the form.

The PSC reviews the forms, determines acceptability of reported activities, and then informs the former trainee or fellow of their status. This process will continue annually until the individual's total payback obligation is satisfied.

11.4.4.3 Change of Address

Any change in the mailing address of a Kirschstein-NRSA recipient must be reported promptly to the PSC until the service obligation is fully discharged. Notification of changes can be made by letter, telephone, fax, or e-mail to NRSAPaybackCenter@mail.nih.gov.

11.4.4.4 Breaks in Kirschstein-NRSA Support

Sometimes a trainee/fellow will have a period of non-Kirschstein-NRSA support between two Kirschstein-NRSA awards. An appropriate activity performed during this period of time may count for payback purposes toward the first Kirschstein-NRSA award. If the nonsupport period is 6 months or

longer, the individual receives an APAC form through the regular mechanism. However, if the break is less than 6 months, an APAC will not be mailed automatically. If acceptable payback service was performed during the break, the individual may complete an APAC, which can be obtained from the NIH web site.

11.4.4.5 National Health Service Corps

A Kirschstein-NRSA recipient may have also been a National Health Service Corps (NHSC) scholar. Kirschstein-NRSA recipients that also have been NHSC scholars are required to fulfill their NHSC service commitment through direct clinical service to the underserved in accordance with NHSC policy. Any Kirschstein-NRSA payback must be fulfilled separately through acceptable Kirschstein-NRSA payback service.

12 RESEARCH CAREER DEVELOPMENT ("K") AWARDS

12.1 GENERAL

This chapter includes general information about research career development awards (CDAs), also known as “K” awards. It supplements the general information found in IIA that applies to all NIH awards.

The objective of NIH career development programs is to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation’s biomedical, behavioral, and clinical research needs. Among NIH ICs, a variety of programs are available for scientists who require additional mentored or independent experience in a productive scientific environment in order to further develop their careers in independent biomedical, behavioral and clinical research.

For mentored programs, support is provided to cover protected time for supervised career development experiences with a goal of leading to research independence. Independent (non-mentored) programs foster the development of outstanding scientists and enable them to expand their potential to make significant contributions to a field of research.

12.1.1 Background

The research CDA program was established in 1961 to enable investigators who have demonstrated research potential to develop further their research careers. The program is authorized by sections 301, 402 and 405 of the PHS Act, 42 U.S.C. 241, 282 and 284. In general, CDAs provide up to five years of salary support and guarantee substantial protected time to engage in research and related activities. The award is available to persons who have demonstrated independent research accomplishments but need additional experience to establish or sustain an independent research program.

12.2 TYPES OF CAREER DEVELOPMENT AWARDS

12.2.1 General

NIH offers a wide variety of CDAs: mentored awards to individuals, including unique career transition programs; non-mentored awards to individuals (mid-career and senior stages), and institutional programs that provide mentored experiences for multiple individuals who are selected by the institution. Some CDAs are linked to other types of NIH awards. Applicants are encouraged to review the FOA for information about IC-specific utilization of the wide variety of CDAs. Specific questions may be directed to the appropriate NIH scientific/research staff or grants management staff named in the FOA.

Further information about specific NIH CDAs is found at the K Kiosk.

12.2.2 Individual Mentored Career Development Awards

Individual mentored CDAs (e.g. K01, K07 (developmental), K08, K22, K23, K25, K99/R00) provide support for a sustained period of “protected time” (generally three, four, or five years) for intensive research career development under the guidance of an experienced mentor or sponsor in the biomedical, behavioral, or clinical sciences. Through the sustained period of research career development and training provided by mentored CDAs, recipients are expected to gain the skills and experience necessary for

independent and productive research careers. Mentored CDAs are not renewable, nor are they transferable from one individual to another. No-cost extensions in time are permitted; however, all terms and conditions, including appointment and minimum effort requirements, remain during the extension period.

Generally, mentored CDA programs are covered by NIH-wide Parent FOAs. In addition, some ICs may issue IC-specific FOAs for specialized programs. Specific program requirements for each mentored CDA program are found in the FOAs. Some programmatic information is provided below for programs with unique policies.

12.2.2.1 Mentor

Individual mentored CDA applications require the candidate to identify a mentor (sometimes referred to as a sponsor) with extensive and appropriate research experience. The candidate must name a primary mentor/sponsor, who, together with the candidate is responsible for the planning, direction, and execution of the program. The mentor should be recognized as an accomplished investigator in the proposed research area; have a track record of success in training independent investigators; and should have sufficient independent research support to cover any costs of the proposed research project in excess of the allowable costs of the CDA award. Candidates may have co-mentors/sponsors as appropriate to the goals of the program. Whenever possible and appropriate, women, individuals from underrepresented racial and ethnic groups, and individuals with disabilities are encouraged to be involved as mentors to serve as role models.

12.2.3 Career Transition Awards

In general, the career transition award programs (K22 and K99/R00) provides protected time through salary and research support to facilitate the transition of postdoctoral individuals or junior faculty in mentored positions to research independence.

12.2.3.1 K22

In general, the K22 program supports two phases of research: 1) a mentored phase (2 years); and, 2) an independent phase (up to 3 years), for a total of up to 5 years of combined support. Some programs, however, support only the newly-independent phase of an investigator's research career development. Applicants for K22 programs need not be affiliated with an applicant institution, e.g., NIH intramural scientists. Planning, direction, and execution of the proposed K22 award are the responsibility of the candidate. Only a few ICs support K22 programs and each has specific eligibility criteria and award provisions. There is no parent FOA.

When the applicant is an intramural scientist, NIH issues a provisional award letter and the actual NoA is issued after identifying a suitable position at an extramural research institution. The position may include continuation of a postdoctoral segment.

12.2.3.2 Pathway to Independence Award (K99/R00)

The objective of the Pathway to Independence Award (K99/R00) is to assist postdoctoral investigators in transitioning to a stable independent research position with independent research funding. The K99/R00 program offers a two-phase award, generally providing up to a total of 5 years of support. Phase I (K99) provides support for up to 2 years of intensive, mentored research career development; Phase II (R00) provides support for up to 3 years of independent research, contingent on securing an independent research position. Phase II is also contingent upon an administrative review and approval by the awarding IC of a transition application.

12.2.3.2.1 Eligibility

The K99/R00 program has several unique eligibility criteria that are not generally applicable to other CDA programs.

- U.S. citizens and non-U.S. citizens with the skills, knowledge and resources necessary to carry out the proposed research and career development activities are eligible to apply.
- K99/R00 applicants must not have more than 4 years of postdoctoral research training as of the relevant application due date regardless of whether it is a new or resubmission application. NIH will consider requests for extension of the K99 eligibility window for various reasons, including medical concerns, disability, family care, extended periods of clinical training, natural disasters, and active duty military service. Each of these requests is reviewed on a case by case basis. NIH will approve an extension of one year for childbirth within the 4 year K99 eligibility window. Applicants who will be PD/PIs on a K99 application must provide the child's date of birth in the extension request justification submitted to IC program officials and/or scientific/research contacts listed in the FOA at least 12 weeks before submitting an application.
- NIH intramural scientists are eligible to apply. If selected for funding, the K99 phase is supported by the NIH IC intramural laboratory in which the candidate conducts research. The R00 phase is supported via an extramural award once an acceptable position at an extramural organization is secured.
- It is expected that K99 recipients will benefit from no less than 12 months of mentored research training and career development before transitioning to the R00 phase.
- If an applicant achieves independence prior to initiating the K99 phase, neither the K99 nor the R00 phase will be awarded.

12.2.3.2.2 K99 Phase

Generally, the K99 phase is for 2 years; however, award recipients may transition earlier than 2 years when the recipient has been offered an acceptable position. It is expected that K99 recipients will receive at least 12 months of career development support from the award before transitioning to the R00 phase. If an applicant achieves independence prior to initiating the K99 phase, neither the K99 nor the R00 phase will be awarded. Recipients are advised to contact the awarding IC if early transition is being considered. In all cases, early transition is considered a prior approval request and therefore subject to the approval of NIH in accordance with Requests for Prior Approval.

Since the K99 and R00 phases are awarded independently, a no-cost extension may be allowed should additional time be needed to complete the goals of the K99 phase. However, no-cost extensions for K99 awards are not automatic and require prior approval by NIH. All terms and conditions of the K99/R00 award (including minimum effort requirements) remain in effect when the grant is in a no-cost extension. In requesting a no-cost extension, K99 recipients wishing to continue to seek a tenure-track or equivalent position should submit a plan for continued career development and a timely transition to an independent position. If an application for the R00 Phase with a suitable position is not submitted within the one-year period of the no-cost extension, the R00 will not be awarded. Those not continuing to seek to transition to the R00 will be permitted to extend without additional funds, in order to permit an orderly phase-out of the project.

Carryover of Funds: Carryover from the K99 phase to the R00 phase may be allowed provided the K99 phase was funded by extramural support. The K99 recipient should consult with the awarding IC as to its practices regarding carryover.

12.2.3.2.3 Transition to the R00 Phase

The K99 award recipient is required to secure a tenure track, full-time assistant professor position or equivalent in order to transition to the R00 independent phase. Transition to the R00 phase is not guaranteed. The transition application for the R00 phase is administratively reviewed by NIH staff and is not peer reviewed by a study section. There should not be any delay between the K99 phase and the R00 phase. R00 award recipients will be expected to compete successfully for independent R01 support from NIH during the R00 phase of the award.

Additional information on the K99/R00 and the FOA are found on the New Investigators Program web page under Pathway to Independence Award: http://grants.nih.gov/grants/new_investigators/#indaward.

12.2.4 Individual Non-mentored (Independent) Career Development Awards

Independent (non-mentored) CDAs (e.g. K02, K05, K07 leadership, K24) provide protected time for scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers. Independent CDAs are intended to foster the development of outstanding scientists and to enable them to expand their potential to make significant contributions to their field of research. Some Independent CDAs also require the candidates to serve as research mentors for junior researchers.

Candidates for independent CDAs must have a doctoral degree and independent, peer-reviewed support at the time the award is made. Some of the participating NIH ICs require candidates to have an NIH research grant from their IC at the time of application. Other NIH ICs will accept candidates with peer-reviewed, independent research support from other sources.

Planning, direction, and execution of the proposed career development program and research project are the responsibility of the applicant and sponsoring institution. Independent CDAs are not transferable from one PD/PI to another. Non-mentored awards are sometimes renewable.

12.2.5 Institutional Scientist Development Programs

The institutional mentored research scientist development program (K12 and KL2) provides support to an institution for the development of independent basic or clinical scientists. The goal is to enhance research career development for individuals (known as ‘scholars’) selected by the institution who are training for careers in specified research areas. A specified number of scholar positions are awarded in a K12. The K12 is solicited only by IC-specific FOAs. Although the K12 is subject to NIH Standard Terms of Award, the carryover of unobligated balances from one budget period to the next generally requires prior written approval. K12 awards are generally not transferable to another institution. When institutional mentored research development programs are incorporated as part of a Clinical and Translational Science Award Consortium the KL2 activity code is used.

The Clinical Research Curriculum Award (K30) is awarded to an institution to stimulate the inclusion of high-quality, multidisciplinary, didactic training as part of the career development of clinical investigators. It supports the development and/or improvement of core courses designed as in-depth instruction in the fundamental skills, methodologies, and theories necessary for the well-trained, independent, clinical researcher.

12.3 ELIGIBILITY

Eligibility can vary depending on the type of award and may even vary by NIH IC within a particular program. However, there are some eligibility criteria which are consistent across all CDA programs and

these criteria are discussed in this section. Candidates are always strongly encouraged to carefully review the eligibility criteria in a specific FOA and to contact the scientific/research and/or grants management contacts in the relevant IC prior to preparing an application to discuss issues of eligibility. These contacts are listed in the individual FOA for each CDA.

12.3.1 Eligible Institutions

Applications for CDAs may be submitted on behalf of the candidate by any domestic commercial or non-profit public or private institution/organization such as universities, colleges, hospitals, and laboratories to support a research program in a specified area(s) of research. Foreign organizations are not eligible to apply for CDAs, but foreign components may apply.

12.3.2 Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research as the candidate (called the PD/PI) is invited to work with their organization to develop an application for a CDA program. Individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are always encouraged to apply for NIH programs. Multiple PD/PI applications are not accepted for individual CDAs; institutional CDAs should check the FOA for the allowability of Multiple PD/PIs.

For mentored CDA programs, candidates who are well-established in their fields are considered ineligible. Some indications of having achieved this status are tenure or the equivalent, a substantial publication record or considerable research support that already requires commitment of a major part of the candidate's time. Applicants who meet one or more of these criteria must provide justification in the application that they are not already established in their field.

12.3.3 Degree Requirements

Degree requirements for CDAs are outlined in the specific FOA. Applicants are generally required to hold a research or health-professional doctoral degree or its equivalent; eligibility for some CDAs is limited to only applicants with health professional doctoral degrees.

12.3.4 Citizenship

For CDA programs other than the K99/R00 program, only U.S. citizens, non-citizen nationals or individuals lawfully admitted for permanent residence at the time an offer of an award is made, are eligible for this award. Individuals on temporary or student visas are not eligible to apply for a CDA unless they have begun the process for becoming a permanent resident and expect to be admitted as a permanent resident by the earliest possible award date. In an application package, on the PHS398 Career Development Award Supplemental Form, the option of selecting “Non-citizen with temporary visa” is applicable to K99/R00 candidates only.

Noncitizen nationals are individuals who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on their passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the applicant organization’s responsibility to follow up and ensure that the candidate receives the I-551 before the 6-month expiration date.

An individual expecting to be admitted as a permanent resident by the earliest possible award date listed in the career award FOA may submit an application recognizing that no award will be made until legal verification of permanent resident status is provided to NIH. The submission of documentation concerning permanent residency is not required as part of the initial application.

Applicants who have been lawfully admitted for permanent residence, i.e., have a Permanent Resident Card or other legal verification of such status, should check the Permanent Resident of U.S. box in Section 3. Citizenship of the PHS398 Career Development Award Supplemental Form. Applicants who have applied for and have not yet been granted admission as a permanent resident or have been granted Conditional Permanent Residency Status should also check the same box.

If a candidate's citizenship status changes after submission of an application, the new status should be reported in the candidate's Personal Profile in the eRA Commons.

In all cases involving any type of Permanent Residency status, when an application is selected to receive an award, prior to any award being issued, a notarized statement will be required that documents that a licensed notary has seen the candidate's valid Permanent Resident Card or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. In all cases where Permanent Residency status is involved, it is the responsibility of the recipient institution to assure the individual remains eligible for the project period of the award.

12.3.5 Type of Appointment

By the time of award, all CDA recipients must have a full-time appointment at the applicant institution. With prior approval from NIH, award recipients may hold part-time appointments for limited periods during the course of their awards (see Temporary Adjustments to the Full-Time Institutional Appointment Requirement below). Full-time or part-time is as defined by applicant institutional policy.

Candidates who hold additional appointments with an independent clinical practice plan, the VA or other organizations should contact the scientific/research and/or grants management contact in the relevant IC prior to preparing an application to discuss their eligibility. Responsibilities outside of the applicant organization appointment are not restricted; however, these types of additional appointments cannot be used to meet the full-time appointment requirement nor the effort requirement discussed below. If a candidate has a dual appointment, they must also have a full-time appointment at the applicant institution to qualify for a CDA.

12.3.5.1 Temporary Adjustments to the Full-Time Institutional Appointment Requirement

Temporary adjustment of the full-time requirement for awarded CDAs is allowed under certain circumstances. At the time of the award, the candidate must meet the full-time appointment requirement (as well as any minimum effort requirement); however, recipients may request a temporary reduction in their appointment to less than full-time (but not less than three-quarter time) for a period not to exceed 12 continuous months during the CDA award project period. Circumstances requiring such a change in appointment status might include personal or family situations such as parental leave, childcare, elder care, medical conditions, or a disability. Permission to change appointment status will not be approved to accommodate job opportunities, clinical practice, clinical training, or joint appointments.

When requesting approval to change to a part-time appointment status, the recipient must continue to commit at least 75% effort (of the part-time appointment) to research and career development activities. The recipient is encouraged to consider increasing their percent effort to greater than 75% (e.g., 85%) to compensate for the anticipated effect of the part-time appointment on the recipient's career progress.

On behalf of the K recipient, the recipient institution must submit a request and documentation to the NIH awarding IC supporting the need for a reduced faculty appointment and assuring the institution's continuing commitment to the scientific and research career development of the recipient. The request should justify reducing the appointment to less than full-time status and must describe the anticipated impact of the requested change on their career progress during the remainder of the award period. In addition, the recipient must submit assurance of their intention to return to a full-time faculty appointment as soon as possible. The mentor must provide a revised mentoring plan and specifically describe updated milestones for the recipient's progression to independence. Lastly, a revised statement of institutional commitment to the recipient must ensure continued "protected time" and describe additional support that will assist the recipient to continue to make progress toward their goals during the requested period of the reduced appointment. During the period of reduced appointment, the salary and other costs supported by the award will be reduced accordingly. Requests must be submitted by the recipient institution to the awarding Institute or Center (IC) where they will be considered on a case-by-case basis.

For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of the award, a request for reduction in the appointment must address the impact of this action on the recipient's ability to make sufficient progress to meet the goals of the program. For example, a K99 recipient must describe how the request will affect the recipient's ability to transition to the R00 phase of the award.

This policy also allows recipients to temporarily reduce the level of effort devoted to the CDA award; that policy is described below in Level of Effort. While these 2 policies are similar in overall goals, an recipient may not simultaneously request a reduction in appointment status from full-time to part-time AND a reduction in percent effort to less than 75%.

12.3.6 Level of Effort

In addition to the full-time appointment requirement described above, mentored and non-mentored CDA recipients are required to devote and maintain a minimum level of effort to the award. During a no-cost extension, the recipient is required to maintain any effort minimum and can only reduce their effort with prior approval of the awarding IC.

CDA recipients who hold additional appointments with an independent clinical practice plan, the VA or other organizations may not use these additional appointments to meet the minimum effort requirement. Responsibilities outside of the applicant organization appointment are not restricted; however, they also cannot be used to meet any minimum effort requirement. If a CDA recipient has a dual appointment, they must also have a full-time appointment at the applicant institution and be able to meet the minimum effort requirement as part of that full-time appointment in order to qualify for a CDA. Candidates are strongly encouraged to contact the scientific/research and/or grants management contact in the relevant IC prior to preparing an application to discuss their eligibility.

12.3.6.1 Mentored CDAs

Mentored CDA recipients are required to devote a minimum commitment equivalent of 9 calendar person months (75% of their full-time appointment at the applicant institution) to the career development and research objectives of the program specified in each FOA. The remaining 3 person months (25% effort), if applicable, can be divided among other research, clinical, and teaching activities only if these activities are consistent with the goals of the mentored CDA, i.e., the recipient's development into an independent investigator. Some NIH ICs allow less than 75% (but not lower than 50%) effort for certain clinical specialties (e.g., surgical and procedure-intensive specialties). Applicants must consult the FOA and also IC Program staff for this exception.

Mentored K recipients are encouraged to apply for additional research grants during the tenure of their K award (see Concurrent Support below). Mentored CDA recipients are allowed to devote complementary effort without salary support on other research grants that include related research between the CDA and the research grant. In such cases where there is scientific overlap, the percent effort on the research grant is subsumed within the required effort of the CDA. However, there should not be significant duplication of the scope of the research supported by the CDA. Further, the related research must be consistent with the goals and objectives of the CDA.

12.3.6.2 Concurrent Support

Provided they remain in a mentored status, mentored CDA recipients in the final two years of their support period are permitted to reduce the level of effort required for the CDA when they have competed successfully for peer-reviewed research awards from NIH or any Federal agency, if programmatic policy of the other Federal agency allows such an arrangement, or non-Federal sources (e.g., foundations or professional societies) of at least $100,000 in direct costs. Recipients are encouraged to obtain funding from NIH or other Federal sources either as a PD/PI on a competing research grant award or cooperative agreement or as a project leader on a competing multi-project award.

Budgets for a competing research grant or a subproject on a multi-project grant should request appropriate amounts for the salary and associated costs for the CDA recipient's effort. At the time the research grant is awarded the effort required on the CDA may be reduced to no less than 6 person months (50% full-time professional effort at the recipient organization) and replaced by effort and corresponding salary from the research award so that the total level of research commitment remains at 9 person months (75% full-time professional effort) or more for the duration of the mentored CDA. This policy applies to the following mentored CDA activity codes: K01, K07 (developmental), K08, K22, K23, and K25, as well as individuals mentored through institutional K12 or KL2 awards. To be eligible for salary support from peer-reviewed research awards from any Federal agency:

- The CDA recipient must be one of the named PD/PIs on a competing NIH research grant application (R01, R03, R15, R21, R34, or equivalent application from another Federal agency) or a sub-project director on a competing multi-component research or center grant or cooperative agreement application (P01, P50, U01, etc. or an equivalent application from another Federal agency).
- The CDA must be active when the competing research grant application is submitted.
- The CDA must be in its final two years before the reduction in effort to 6 person months (50% full-time professional effort) is permitted.

For submissions to NIH, a letter must accompany the research grant application from the chair of the mentored award recipient's department or other responsible institutional official providing: (1) evidence that the recipient will continue to focus on the development of their research career; (2) will continue to have access to their mentor; and (3) that the recipient's total level of research effort will be maintained and protected at a minimum of 9 person months (75% full-time professional effort). For submissions to other Federal agencies, this type of institutional commitment letter is strongly encouraged; however, applicants should check with that agency for guidance on the allowability of such a letter.

When a mentored CDA recipient obtains independent support, as described above, the NIH awarding IC supporting the CDA will adjust the level of effort committed to the CDA to no less than 6 person months (50% effort) consistent with maintaining total research effort at 9 person months or 75% or more of the full-time appointment. NIH will adjust the total salary support committed to the K award consistent with the adjusted level of effort. However, NIH will continue to provide full research development support costs (i.e., Other Personnel, Equipment, Travel, Participant/Trainee Support, and Other Direct Costs

budget categories) as indicated on the original Notice of Award. If necessary, the K award may also be adjusted to avoid any additional budget overlap.

12.3.6.3 Non-mentored CDAs

Established investigators on independent (non-mentored) CDAs are generally required to devote a minimum of 3-6 person months (25-50% effort) conducting research and research career development related activities during the period of the award. Some independent CDAs allow and may require more than 6 person months (50% effort). For example, K02 recipients are required to devote 9 person months (75% effort) to research.

Generally, an independent or leadership recipient may receive additional salary support from other NIH/PHS grants for effort not committed to the CDA and there are no limitations to receiving other salary support. Where applicable, specific policies are noted in the FOA. The candidate must be able to demonstrate that the requested period of salary support and protected time will foster their career and capacity to contribute to the specified field.

12.3.6.4 Temporary Adjustments to the Percent Effort Requirement

At the time of the CDA award, the candidate must still meet the applicable effort requirement (as well as the full-time appointment requirement); however, under certain circumstances, recipients may request a temporary reduction in their effort for a period not to exceed 12 continuous months during the award project period. For programs that require a 75% effort minimum (equivalent to 9 person months), an recipient can request a reduction to no less than 50%. Circumstances requiring such a change in effort might include personal or family situations such as parental leave, childcare, elder care, medical conditions, or a disability. Permission to temporarily reduce effort will not be approved to accommodate job opportunities, clinical practice, clinical training, or joint appointments.

On behalf of the K recipient, the recipient institution must submit a request and documentation to the NIH awarding IC supporting the need for reduced effort and assuring the institution's continuing commitment to the scientific and research career development of the recipient. The request should justify reducing effort and must describe the anticipated impact of the requested change on their career progress during the remainder of the award period. In addition, the recipient must submit assurance of their intention to return to 75% effort as soon as possible. The mentor must provide a revised mentoring plan and specifically describe updated milestones for the recipient's progression to independence. Lastly, a revised statement of institutional commitment to the recipient must ensure continued "protected time" and describe additional support that will assist the recipient to continue to make progress toward their goals during the requested period of the reduced appointment. During the period of reduced effort, NIH will adjust the total salary amount committed to the K award consistent with the adjusted level of effort. However, NIH will continue to provide full research costs in other budget categories as indicated on the original Notice of Award. In addition, the K recipient may request to extend the duration of the award to account for the reduced effort. Requests must be submitted by the recipient institution to the awarding Institute or Center (IC) where they will be considered on a case-by-case basis.

This option is not available for Independent CDAs that require only 25-50% effort; e.g., K07 leadership, K05, and K24.

While this temporary adjustment in effort policy is similar to the policy described above allowing a temporary adjustment in the full-time appointment requirement, recipient may not simultaneously request a reduction in appointment status from full-time to part-time AND a reduction in percent effort to less than 75%.

12.3.7 Prior Research Support

For most mentored career development awards, individuals are eligible to apply if they have previously served as the PD/PI of an NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Planning Grant (R34/U34), Dissertation Award (R36), SBIR/STTR Award, Transition Scholar Award (K38) or been appointed to an institutional career development program (K12, KL2). The K99/R00 program, however, has different eligibility requirements related to prior research support and those are detailed in the funding opportunity announcement.

In general, for mentored CDAs, individuals are NOT eligible if they:

- Are current and former PDs/PIs on NIH research project (R01), program project (P01), center grants (P50), other major individual career development awards (e.g., DP5, K01, K07, K08, K22, K23, K25, K76, K99/R00), or
- Project Leads of program project (P01) or center grant (P50) sub-projects, or the equivalent.

Most independent (non-mentored) CDAs require that the applicant have independent, peer-reviewed support at the time the award is made. Some of the participating NIH ICs require the candidate to have an NIH research grant at the time of application and that the support be from their IC. Other NIH ICs will accept candidates with peer-reviewed, independent research support from other sources. Applicants must check the FOA for specific eligibility requirements.

12.4 APPLICATION REQUIREMENTS AND DUE DATES

12.4.1 Application

Before applying for a CDA, applicants should carefully review the guidelines in the FOA for the specific career award(s) of interest, noting especially the eligibility requirements, award provisions, requirements for a mentor, and review criteria. The participating ICs may have distinctive guidelines, requirements, and funding amounts for each FOA in order to accommodate the career needs of researchers working in fields related to their specific research missions. Candidates are therefore strongly encouraged to contact the staff person in the relevant IC listed in the FOA prior to preparing an application to discuss any specific provisions of the award.

The specific FOA provides links to the application forms package as well as the appropriate application instruction guide. As with all NIH programs using electronic submission, a CDA application uses a combination of SF424(R&R) and PHS398 forms. A separate section (Section I.7) of the SF424(R&R) Application Guide is included that provides supplemental instructions for preparing a CDA application. Further assistance is available from GrantsInfo.

Applications must contain Candidate Information, Statements of Support, Environment and Institutional Commitment to the Candidate, as well as a Research Plan. The Candidate Information section includes required information about the candidate and must justify the need for the requested period of support, be tailored to the prior research experience and career development needs of the candidate, and for mentored CDAs be designed to move the candidate from a mentored phase to an independent status. The research plan must have intrinsic research importance as well as serve as a suitable vehicle for learning the methodology, theories, and skills necessary for a well-trained independent researcher. For mentored award programs, the research plan must also include a description of the relationship between the mentor's research and the candidate's proposed research plan.

Other than the K22 application from an unaffiliated candidate, all applications require documents describing the Environmental and Institutional commitment to the candidate.

For mentored award programs the career development application also must include Statement by Mentor(s), Co-Mentor(s), Consultant(s) and Contributor(s) as well as a statement describing the institution's commitment to the candidate's development.

The requirement for ORCID identifiers will be enforced at the time of application for individual career development awards, including the following: K01, K02, K05, K07, K08, K18, K22, K23, K24, K25, K26, K38, K43, K76, and K99/R00.

eRA system validations will check whether applicants have ORCID iDs and applications will not be accepted unless an ORCID iD is linked to the PD/PI's eRA Commons Personal Profile.

To either link their eRA profiles to existing ORCID accounts or create ORCID profiles and link them back to the eRA Commons. Prospective applicants for individual career development awards may follow the ORCID link from their Personal Profiles in the eRA Commons.

12.4.1.1 Letters of Reference

At least three (but no more than five) letters of reference are required for all new and resubmission mentored CDA applications. The letters should be from individuals not directly involved in the application, but who are familiar with the candidate's qualifications, training, and interests and include advisory committee members (if applicable). However, the candidate's mentor(s) of the application must not submit a separate letter of reference because a mentor's statement is required as part of the application. The letters of reference should address the candidate's competence and potential to develop into an independent biomedical, behavioral, or clinical investigator.

Electronic submission of CDA applications requires electronic submission of reference letters as well. However, reference letters are submitted directly by the referee through the eRA Commons and not as part of the electronic application that goes through Grants.gov. Reference letters will be joined with the electronic application within the eRA system once an application completes the submission process. Applications that are missing the required letters may be delayed in the review process or not accepted at all. Complete instructions for candidates and referees are found in Part I, Section 7.3 of the SF424(R&R) Application Guide for Adobe Applications.

12.4.1.2 Concurrent Applications

NIH will not accept any application in response to an FOA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial resubmission of an application already reviewed, but such applications must include an Introduction addressing the previous critique.

12.4.1.3 Environment and Institutional Commitment to the Candidate

The applicant organization must define and document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with staff capable of productive collaboration with the candidate. The institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of the award. The institution should indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in the application. The applicant should describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

The institution should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development. The document should include the institution's

agreement to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured research career development experience. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award.

Because of the diverse types of CDAs, applicants should contact the appropriate awarding IC scientific/research contact named in the specific FOA to determine the level of commitment required for the application. Institutional commitment to the candidate may not be contingent upon the receipt of the CDA.

Off-Site Training Experience. A candidate may propose a career award experience that involves sites beyond the applicant organization, provided that the goals of the total experience are encompassed and supported under the appointment with the applicant organization.

12.4.1.4 Training in the Responsible Conduct of Research

All CDA applicants (mentored and non-mentored) must include a description of the formal and informal activities related to instruction in the responsible conduct of research planned for the proposed research program. Specifically, applicants must include a description of a plan for instruction in responsible conduct of research. This description should document prior instruction in or the nature of the applicant's participation in responsible conduct of research instruction (lecturer, discussion leader, etc.) during the applicant's current career stage (including the dates of last occurrence) and propose plans to receive or participate in instruction in responsible conduct of research. Such plans must address the five instructional components, format, subject matter, faculty participation, duration of instruction, and frequency of instruction, as outlined below. Applications lacking a plan for instruction or participation in responsible conduct of research will be considered incomplete and may be delayed in the review process. Plans and past record will be rated as **acceptable** or **unacceptable** and the summary statement will provide the consensus rating of the review committee. Applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan. For additional information see the specific FOA.

1. ***Format.*** Discussion-based instruction in the responsible conduct of research is expected to remain a key feature of RCR training and to include substantive face-to-face interaction among participants and faculty. However, recognizing that advances in video conferencing now allow for effective "face-to-face" discussions to occur electronically, institutions may wish to consider incorporating video conferencing options into their RCR instruction, provided that those options are utilized in a way that fosters discussion, active learning, engagement, and interaction among the participants. At the same time, video conferencing should not be the sole means for meeting the requirement for RCR instruction, and a plan that employs only video conferencing will not be considered acceptable, except in special instances of short-term training programs (see below), or unusual and well-justified circumstances.

2. ***Subject Matter.*** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

(a) conflict of interest – personal, professional, and financial – and conflict of commitment, in allocating time, effort, or other research resources

(b) policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices

(c) mentor/mentee responsibilities and relationships

(d) safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)

(e) collaborative research including collaborations with industry and investigators and institutions in other countries

(f) peer review, including the responsibility for maintaining confidentiality and security in peer review

(g) data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks;

(h) secure and ethical data use; data confidentiality, management, sharing and ownership

(i) research misconduct and policies for handling misconduct

(j) responsible authorship and publication

(k) the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all aspects of responsible research conduct.

3. ***Faculty Participation.*** Mentors and other appropriate faculty are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. For institutional Career Awards, training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.

4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the career recipient/scholars, mentors and other appropriate faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Existing policy and guidance call for RCR instruction to be undertaken at least once during each career stage, and at a frequency of no less than once every four years. As institutions consider how to optimize the timing and delivery of instruction in the responsible conduct of research, they are encouraged to bear in mind the value of ongoing and discipline-specific training as individuals progress in their research careers. For example, while broad-based instruction in the responsible conduct of research is often appropriate early in graduate school; a more tailored, discipline-specific approach may better fit the needs of advanced graduate students and those who have transitioned to postdoctoral status. If advanced students and postdoctorates have been exposed to the full range of topics traditionally included in RCR instruction early in their scientific training, it may make sense for their ongoing and/or subsequent RCR training to focus on subjects most relevant to their fields, and institutions may wish to consider this approach, where applicable.

12.4.1.5 Budget

CDAs provide limited costs, generally covering only applicable salary and fringe benefits for the candidates, as well as a fixed amount for research development support. Costs requested and awarded for

CDA programs must be consistent with applicable Federal cost principles. Salary amounts as well as the research development costs can vary by CDA program and then within a particular program even by each participating NIH IC. Applicants are advised to consult the relevant FOA for guidelines on allowable costs and budget limitations.

The transition to electronic submission included a change in business process with respect to budget information. Detailed budget information is now required as part of the initial application; however it is limited to the senior/key person information for only the candidate and then the total amount of requested research development support in budget section F.1. Other Direct Costs/Materials and Supplies. A budget justification is also required and should be used to provide a detailed description for the specific research development support costs. Instructions are provided in the applicable Application Guide and specific FOAs.

As with all NIH training programs, Facilities and Administrative costs for CDAs are provided at a rate of 8% of modified total direct costs.

12.4.1.6 Submission Dates

For all parent CDA FOAs, NIH receives applications three times each year using standard submission dates. For a list of the standard submission dates and review cycle are posted on NIH's web site. IC-specific FOAs may use special submission dates instead of the standards dates, but the FOA will clearly indicate if standard or special submission dates are used.

12.5 REVIEW

All CDA applications will undergo peer review as noted in The Peer Review Process in Part I; however, the actual review criteria and other review considerations are different as described herein.

12.5.1 Overall Impact

Reviewers should provide their assessment of the likelihood for the candidate to develop and/or maintain a strong research program, taking into consideration the criteria below in determining the overall impact score.

12.5.2 Scored Review Criteria

For CDA applications, reviewers will consider each of the five review criteria below in the determination of the scientific and technical merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have a major scientific impact. The scored criteria are:

- Candidate
- Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
- Research Plan
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s); and for non-Mentors the Mentoring Plan
- Environment and Institutional Commitment to the Candidate

These criteria are listed in logical order and not in order of priority. Since the specifics for each of these criteria can vary for the various CDA programs, the review criteria are described in detail in the FOA. Note that different ICs may employ additional review criteria.

12.5.3 Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- Protection of Human Subjects
- Inclusion of Women, Minorities and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards
- Resubmission Applications
- Renewal Applications
- Revision Applications

The FOA should be consulted for further information describing each of the relevant additional review criteria.

12.5.4 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- Training in the Responsible Conduct of Research
- Select Agents
- Authentication of Key Biological and/or Chemical Resources
- Resource Sharing Plans
- Budget and Period of Support

Candidates should carefully review the applicable FOA for complete information associated with the peer review process including further information describing each of the relevant additional review considerations.

12.6 NOTIFICATION OF ACTION

Shortly after the initial peer review meeting, candidates receive an e-mail indicating that the SRG recommendation/impact score is available in the eRA Commons. The candidate is also notified via an e-mail when the summary statement (written critique) is available in the eRA Commons.

The PO may notify the applicant about the final review recommendation. The applicant should direct any questions about initial review recommendations and funding possibilities to the designated IC PO, not the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons. If the application is under consideration for funding, NIH will request additional information. After all program and administrative issues have been resolved, the NoA will be issued for those applications selected for funding.

12.7 PERIOD OF SUPPORT

The NIH awarding IC will notify the individual of the intention to make an award and confirm the plans for the start of support. An award is for a period of 3 to 5 years and provides support for salary and

research-development support costs. Support beyond the first year shall be based on an assessment by NIH staff of the effectiveness of the development opportunity and continued opportunity for growth, as reflected in the recipient's annual progress report. Continuation of awards is contingent upon future Federal appropriations.

Mentored CDAs are not renewable. Non-mentored CDAs may be renewable; awards may be competitively renewed at the discretion of the participating NIH ICs. Only a few of NIH ICs permit competitive renewals.

Note the period of support for the K99/R00 program is awarded in 2 distinct phases. Phase I covers only the K99 period; phase II is the R00 portion and is contingent upon meeting certain criteria, including the submission and acceptance of a R00 application by the NIH IC.

Some K22 programs also have 2 distinct funding phases where specific criteria must be met before funding is provided for the second phase.

Note, the K99/R00 and some K22 programs allow NIH intramural scientist to apply. For those selected for funding, the period of support on any award issued will only reflect the period funded by NIH extramural funds. Any period of support supported by NIH intramural funds will not be evident in the NoA.

12.8 ALLOWABLE AND UNALLOWABLE COSTS

Policies included in the applicable cost principles in 2 CFR Part 200, Subpart E and the NIHGPS govern the expenditure of all CDA funds, unless otherwise indicated in the NoA.

12.8.1 Salaries and Fringe Benefits

Requested salary and fringe benefit amounts must be in accordance with institutional policies applied consistently to individuals in like circumstances and must be supported by acceptable accounting principles. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure. Salary amounts requested on CDA grants must be based on the investigator's institutional base salary (IBS) prorated for their commitment on the project. While requested salary and fringe benefit information is provided in the initial application, confirmation of these costs may be required prior to the issuance of an award.

The amount funded as salary for a CDA is not uniform throughout the NIH participating ICs. Salary limits vary by IC and are noted in the FOA. Note the limit is on salary only; applicable fringe benefits are provided in addition to the salary. The candidate is strongly advised to contact the relevant awarding IC for any distinct guidelines, requirements, and allowable funds. Salary costs charged cannot exceed the applicable legislative salary cap.

The recipient institution may supplement the NIH salary contribution on the CDA up to a level that is consistent with the institution's salary scale. For effort directly committed to the CDA, salary supplementation is allowable, but must be from non-Federal sources (including institutional sources). In no case may PHS funds be used for such salary supplementation. Non-federal or institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the goals of the CDA. For effort not directly committed to the CDA, CDA recipients may devote effort, with compensation, on Federal or non-Federal grants as the Program Director/Principal Investigator (PD/PI) or in another role (e.g., co-Investigator), as long as the specific aims of the other supporting grant(s) differ from those of the CDA.

NIH IC limitations on awarded salary levels do not limit the recipient's rebudgeting authority. Institutions may rebudget the total costs awarded to cover additional salary charges, provided they are within

the approved scope of the project and consistent with the institution's salary scale as long as the cost charged is within the applicable legislative salary cap.

Salary support for ancillary personnel (e.g. administrative assistance or secretarial support) on CDAs is not allowable.

Salary support for mentors is not allowable on individual mentored CDAs.

Salary support for research technicians or study coordinators for clinical studies are generally allowable but are budgeted as part of the Research Development Support Costs described below.

12.8.2 Research Development Support Costs

CDAs may include a fixed amount for research development support costs. This amount may vary by IC and is commonly used for supplies, equipment, technical personnel, travel to research meetings or training, tuition/fees for courses and computational services.

12.8.3 Proposal Preparation Costs

Mentored CDA programs provide support with a goal of leading to research independence for an individual. Since research independence is achieved through applying for other research support, consistent with these objectives, it is allowable for effort devoted to proposal preparation costs for subsequent research support to be charged to a mentored CDA award. This can be considered part of the awarded effort commitment of the mentored CDA or an increase to that commitment with the allowable salary provided as applicable.

12.8.4 Facilities and Administrative Costs

For career awards other than the R00 phase of the K99/R00 and other than State, local, or Indian tribe (or "federally recognized Indian tribes"), recipients will receive F&A costs at 8 percent of modified total direct costs. State and local agencies, and Indian tribes (or "federally recognized Indian tribes") are eligible for full F&A cost reimbursement. For this policy, State universities or hospitals are not considered governmental agencies.

12.9 REBUDGETING OF FUNDS

Funds awarded on CDAs may typically be rebudgeted within direct cost categories without prior approval; however restrictions on rebudgeting may be noted in the NoA.

Rebudgeting of salary funds in an NIH-supported research grant for the salaries or fringe benefits of individuals which are freed as a result of a career award, may not be rebudgeted without the prior approval of the NIH awarding IC.

12.10 CARRYOVER AUTHORITY

Unless otherwise noted by a specific term of award, Individual CDAs have automatic carryover authority. However, for most Institutional CDAs, carryover requires prior approval. The NoA will specify whether or not the recipient must obtain prior approval to carry over funds.

For the two-phased K99/R00 program, carryover from the K99 phase to the R00 phase may be allowed provided the K99 phase was funded by extramural support. The K99 recipient should consult with the awarding IC as to its practices regarding carryover.

12.11 REPORTING REQUIREMENTS

Failure to comply with reporting requirements and to submit the required forms in a timely manner may result in an expenditure disallowance or a delay in any continuation funding.

12.11.1 Progress Reports

Most individual CDA awards (mentored and non-mentored) are awarded under SNAP authorities. Progress reports for SNAP awards must be submitted using the Research Performance Project Report (RPPR). The RPPR must be submitted electronically using the RPPR module in the eRA Commons. For progress reports submitted using the RPPR, the IDP requirement described in Non-Competing Continuation Progress Reports will apply. Progress reports for non-SNAP awards should be submitted in accordance with the PHS 2590 instructions, including Section 4, Additional Instructions for Preparing Continuation Career Development Award (CDA) Progress Reports. PHS 2590 progress report forms and instructions are available from the NIH Web site.

Following completion or termination of a project period, the recipient must submit a Final RPPR to the NIH awarding IC within 120 days after the end of grant support as part of the Closeout documents described below.

12.11.2 Federal Financial Report

For individual CDAs awarded under the SNAP authorities, an annual electronic FFR is not required. Only a final FFR is required at the end of the project period (see Administrative Requirements—Monitoring—Reporting—Financial Reports and Administrative Requirements—Closeout—Final Reports in IIA).

12.11.3 Closeout

The Closeout requirements included in IIA (see Administrative Requirements—Closeout—Final Reports) apply to all Individual CDAs (mentored and non-mentored). For Institutional Scientist Development Programs the closeout requirements apply with the exception of the Final Invention Statement; invention reporting is not applicable to K12s & KL2s thus a final invention statement is not required as part of the closeout process.

12.11.4 Post Closeout Evaluation

In carrying out its stewardship of human resource-related programs, NIH may request information essential to an assessment of the effectiveness of CDA programs. Accordingly, CDA recipients may be contacted after the completion of any CDA award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

12.12 CHANGES IN THE PROJECT

The approval of the NIH awarding IC is required for a transfer of the CDA to another institution, or a project change. Note, individual mentored and non-mentored CDAs may not be transferred to another PD/PI.

The Change of Recipient Organization policies described in IIA apply to Individual CDAs as long as the transfer is between domestic institutions. For mentored CDAs, the recipient must have a mentor at the new institution. If the transfer also involves a change in mentor, supporting documentation from the new

mentor will be required. Consultation with the applicable NIH program staff and/or grants management staff is strongly encouraged when a change of institution is being considered.

CDAs are awarded under the NIH Standard Terms of Award and as such recipients have the authority to extend the final budget period of a project period without additional funds for up to 12 months. Recipients are reminded that all terms and conditions and programmatic requirements apply during the extension period. For instance, the full-time appointment and minimum effort requirements must continue for the entire extension period. Recipients should be mindful of these requirements when deciding how much additional time is needed.

12.12.1 Temporary Off-Site Career Development Experience

A temporary career development experience at another institution, including a foreign laboratory, may be permitted if the proposed experience is directly related to the overall goals and purpose of the K award. Only local institutional approval is required if such an arrangement does not exceed 3 months. For longer periods (not to exceed 12 months), prior written approval from the NIH awarding IC is required. The written request must document the approval of the recipient organization and the adequacy of arrangements for off-site training. Support from the career award will continue during such an off-site experience. For some CDAs additional information is required as part of any prior approval request:

- For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of each of these awards, a request for approval of an off-site training experience lasting more than 3 months must address the impact of such action on the recipient's ability to make sufficient progress to meet the goals of the award. For example, for a K99 phase recipient, the request must describe how the off-site experience will affect the recipient's ability to transition to the R00 phase.
- For K05, K07 leadership, and K24 recipients, the request must include a letter assuring that arrangements have been made to continue to commit the appropriate effort to the research and to provide mentoring.
- For K12 and KL2 Scholar appointees, because of the short duration of the mentored phase of each of these awards, a request for approval of an off-site training experience lasting more than 3 months must address the impact of such action on the scholar's ability to make sufficient progress to meet the goals of the program.

12.13 OTHER TERMS AND CONDITIONS

Except as otherwise noted below, the provisions of IIA apply to all CDA programs. This includes all Public Policy Requirements, Objectives, and Other Appropriation Mandates such as civil rights; the protection of human subjects, including data and safety monitoring requirements; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant or synthetic nucleic acid research. See Subpart IIA for a complete list of applicable requirements.

In addition, all Administrative Requirements described in IIA also apply to CDA program unless an exception is noted below. These include requirements such as prior approvals; availability of research results, publications, NIH Public Access policy, invention reporting, and program income. See IIA for a complete list of applicable administrative requirements.

Leave

Since CDA recipients are employees of the institution, applicable institutional leave policies for leave such as vacation, sick, parental, etc. apply to individuals supported by NIH CDAs.

CDAs are expected to be for continuous support of an individual; however, in certain circumstances, candidates will be permitted to take a leave of absence. Circumstances include personal or family situations such as parental leave, childcare, elder care, medical conditions, or a disability. A leave of absence or sabbatical greater than three months must be requested and approved in writing by the NIH awarding IC. A leave of absence less than 3 months only requires institutional prior approval.

For some CDAs additional information is required as part of any prior approval request:

- For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of each of these awards, a request for approval of a leave of absence lasting more than 3 months must address the impact of such action on the recipient's ability to make sufficient progress to meet the goals of the award. For example, a K99 phase recipient must describe how the leave will affect the recipient's ability to transition to the R00 phase.
- For K05, K07 leadership, and K24 recipients, the request for a leave of absence lasting more than 3 months must include a letter assuring that arrangements have been made to continue to commit the appropriate effort to the research and to provide mentoring.
- For K12 and KL2 Scholar appointees, because of the short duration of the mentored phase of each of these awards, a request for a leave of absence lasting more than 3 months must address the impact of such action on the scholar's ability to make sufficient progress to meet the goals of the program.

12.13.0.1 Unpaid Leave

Leave without award support may not exceed 12 months. Such leave requires prior written approval of the awarding component and will be granted only with justification. When approved, the K award will be placed in a no-cost extension for the duration of the unpaid leave and no charges to the grant will be allowed during that period, although continued coverage of health insurance would be allowable if in accordance with institutional policy. Such leave does not reduce the total number of months of program support for which an individual is eligible.

12.13.1 Statement of Appointment—Institutional CDAs Only

At the time of the initial appointment of K12 or KL2 scholars, the Program Director may submit a Statement of Appointment (Form PHS 2271) for each scholar to the NIH awarding IC to document the appointment of scholars to institutional CDAs. This policy varies with ICs and is specified in the Funding Opportunity Announcement. When 2271s are required, this information must be submitted using the xTrain feature in the eRA Commons.

12.13.2 Early Termination

Consultation with the applicable NIH program staff and/or grants management staff is strongly encouraged when a termination is being considered before the scheduled project end date. When an institution plans to terminate an award, the awarding IC must be notified in writing at the earliest possible time, so that appropriate instructions can be given for termination. NIH will issue a revised NoA to specify the changed period of support.

NIH may terminate a CDA before its normal completion date if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. If an award is terminated, NIH will notify the recipient in writing of the determination, the reasons for the determination, the effective date, and the right to appeal the decision.

The NIH awarding IC should be notified immediately if a sponsoring institution wants to terminate a K12 scholar, or if the scholar decides to terminate the appointment before the scheduled completion date.

12.13.3 Other Income: Generation and Disposition of Professional Fees

CDA recipients may retain royalties and fees from activities such as scholarly writing, service on an advisory group, honoraria from other institutions for lectures or seminars, fees resulting from clinical practice, professional consultation, or other comparable activities, provided these activities remain incidental, are not required by the research and research-related activities of the CDA, and provided that the retention of such pay is consistent with the policies and practices of the recipient institution. No other income or fees may be retained by the CDA recipient and must be assigned to the recipient institution for disposition by any of the following methods:

- The funds may be expended by the recipient institution in accordance with NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the recipient institution.
- The funds may be used for health-related research purposes.
- The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services and forwarded to the Director, Office of Financial Management, NIH, Bethesda, MD 20892. Checks must identify the relevant award account and reason for payment.

Adequate records regarding the source, receipt and disposition of fees and other income are to be maintained by the institution for the applicable retention time period(s) specified in 2 CFR Part 200.307 and 45 CFR Part 75.307.

13 MODULAR APPLICATIONS AND AWARDS

13.1 GENERAL

Modular applications and awards employ a simplified process for developing and reviewing application budgets, documenting approved budgets, and making post-award budgetary changes.

13.2 APPLICABILITY

Modular procedures are required to be used for new, renewal, and resubmission applications as well as for revisions for the following grants and their cooperative agreement equivalents that request up to a total of $250,000 of direct costs per year (excluding consortium F&A costs), regardless of whether the application is an investigator-initiated application or is one submitted in response to a PA/RFA: Research Project Grants Program (R01/U01), Small Grant Program (R03), Exploratory/Development Research Grant Award (R21/UH2), Clinical Trial Planning Grant Program (R34/U34) and Academic Research Enhancement Awards (R15/UA5). Modular procedures do not apply to SBIR and STTR Phase I grants (R43 and R41), and do not apply to foreign (non-U.S.) organizations.

Instructions for specific grant mechanisms other than the R01 and guidelines for IC programs may indicate a particular number or range of modules allowed.

Modular applications and awards may also be subject to other simplified procedures, specifically Just-in-Time requirements and SNAP.

13.3 APPLICATION REQUIREMENTS

Modular applications must be submitted on the SF424 (R&R) forms. Paper-based applications that include modular budgets will no longer be accepted.

13.3.1 Budget

Modular applications request direct cost funding in modules of $25,000, for up to $250,000 each year for covered activity codes. F&A costs for subcontracts are not included in determining the direct cost modular amount or the total cost amount requested. The modules should be a reasonable estimate of allowable, allocable, and reasonable costs for the proposed project. In addition, F&A costs at the negotiated rate for the applicant institution are also allowable.

Since only limited budget information is required for submission of a modular application, the PHS 398 Modular Budget Component, which is included as part of the electronic SF424 (R&R) form set, must be submitted to NIH through Grants.gov. Sample modular application budget pages are available at NIH's web site. The standard SF 424 Research and Related Budget Component is not used for application using modular budgets.

The PHS 398 Modular Budget Component includes information on direct costs modules as well as F&A costs; budget justifications for all personnel by position, role, and level of effort (measured in person months); consultants; and ‘to be appointed’ positions. No individual salary information should be provided. Applicants must use the current legislatively imposed salary limitation when determining the number of modules to request (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages in IIA). Given the authority to rebudget and carry forward unobligated balances, funds generally should be available to cover modest increases in any statutorily imposed salary cap. NIH also limits the compensation for graduate students. Compensation includes salary or

wages, fringe benefits, and tuition remission. These limits should be used when estimating the number of modules. See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages in IIA for more information on compensation of graduate students.

When applicable, a separate budget justification must address consortium/contractual costs (including applicable F&A costs) rounded to the nearest $1,000. The narrative should list the individuals and organizations with whom consortium or contractual arrangements have been (or will be) made, the level of effort of senior/key personnel (measured in person months) and their role on the project, and indicate whether the collaborating organization is foreign or domestic.

A typical modular application will request the same number of modules for each year. However, well-justified modular increments (up to the $250,000 modular ceiling) or decrements in the total direct costs for any year of the project that reflect substantial changes in expected future activities may be requested at the outset. For example, a major equipment purchase in the first year may justify a higher overall budget in that year, but not necessarily in succeeding years. There is no provision for escalation in future years. NIH requires additional narrative budget justification if there is a variation in the number of modules requested from year to year. Further, when the pre-award review warrants such a request, NIH ICs may request a detailed budget as part of the Just-in-Time process.

13.4 APPLICATION REVIEW AND AWARD

SRGs evaluate the budget on the basis of a general, expert estimate of the total effort and resources required to carry out the proposed research. If the SRG recommends an adjustment in the project budget, the recommended adjustment will be in terms of an entire module.

Following peer review, for applications being considered for award, the IC will request information about "Other Support" and, as applicable, the use of human subjects or vertebrate animals, and education in the protection of human research participants. Additional budget information will be requested before award only under special circumstances.

NIH will attempt to make awards at or close to the level of total direct costs recommended by the SRG, taking other support into account. An IC may need to reduce the award amount to accommodate the IC's cost management plan.

The award budget will be a noncategorical budget specifying approved total direct costs and F&A costs, if applicable.

13.5 POST-AWARD ADMINISTRATION

Recipients have discretion in determining how to allocate and account for costs related to modular awards within their organizational accounting system. However, institutions are still required to ensure that all costs charged to modular awards are in accordance with applicable costs principles, the NIH GPS, and any legislatively imposed restrictions.

Modular awards are subject to the standard NIH Terms of Award and may be awarded under the SNAP authorities. However, since the award is issued without direct cost budget categories, the significant rebudgeting provision described as a potential change of scope indicator does not apply to modular grants.

Recipients may submit requests for administrative supplements to the CGMO of the NIH awarding IC, but must provide a detailed (non-modular) budget.

Competing Revisions should be submitted to NIH using the modular budget component.

14 SUPPORT OF SCIENTIFIC MEETINGS (CONFERENCE GRANTS)

14.1 GENERAL

NIH supports scientific meetings, conferences, and workshops (hereafter "conferences") that are relevant to its scientific mission and to public health under the R13 and U13 activity codes. NIH's support of conferences is contingent on the interests and priorities of the individual ICs. Most ICs provide conference support although their budget guidelines may vary. Prior approval (advance permission) is required before submission of an application for conference support. Advance permission to submit an application must be requested early in the process and no later than 6 weeks before the application submission date. Permission to submit a conference grant application does not assure funding or funding at the level requested. The letter from the NIH IC conference grant contact person documenting advance permission to submit an application must be included as part of the PHS 398 Cover Letter component of the application. Potential applicants must contact the funding IC before submission for specific information as well as to ensure compliance with submission requirements. Applications for conference support must be submitted based on the published receipt dates. In general, NIH will not issue a conference grant award unless the Federal award date can precede the conference start date. Awarding a conference grant after a conference has been held should only be done when an IC can determine or document that funding of post-conference activities is consistent with the approved application.

14.2 APPLICABILITY

This chapter applies to grants that support domestic and international conferences. If a policy is not addressed in this chapter, then IIA coverage applies.

Questions concerning the allowability of conference activity under research grants should be directed to the GMO.

14.3 DEFINITIONS

Conference (in general). 2 CFR Part 200.432 and 45 CFR Part 75.432 defines a conference as a meeting, retreat, seminar, symposium, workshop or event whose primary purpose is the dissemination of technical information beyond the non-Federal entity and is necessary and reasonable for successful performance under the Federal award.

Scientific Meeting (Conference). A gathering, symposium, seminar, workshop, or any other organized, formal event where people assemble to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge.

International Conference. A scientific meeting so designated by its sponsor or one to which open invitations are issued on an equal basis to potential participants in two or more countries other than the United States or Canada. The meeting may be held in the United States or any country, subject to U.S. Department of State travel restrictions.

Domestic Conference. A scientific meeting held in the United States or Canada primarily for U.S. or U.S.-Canadian participation (even if foreign speakers are invited).

14.4 ELIGIBILITY

Domestic institutions or organizations, including established scientific or professional societies, are eligible to apply for conference support. Both domestic and international conferences may be supported; however, an international conference may be supported only through the U.S. representative organization of an established international scientific or professional society. An individual is not eligible to receive a grant in support of a conference.

14.5 APPLICATION REQUIREMENTS

Conference grant applications are electronically submitted using an application package that combines SF424 (R&R) and PHS398 components. Applications packages and instructions are provided with each FOA. Applicants must complete and submit a detailed categorical budget using the Research & Related Budget component; however, no indirect (F&A) costs may be requested. The appropriate NIH IC Conference Grant Contact should be consulted for guidance regarding any IC-specific budget and project duration requirements. R13 and U13 applicants should describe in the Personal Statement of the Biographical Sketch senior/key persons' past experiences with enhancing diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups, in biomedical sciences. Application requirements and further information on NIH support for conferences and scientific meetings (R13 and U13) may be found on the NIH Web site at http://grants.nih.gov/grants/funding/r13/ or in applicable FOAs.

14.6 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

In addition to any applicable public policy requirements and objectives specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA, the following apply to NIH Conference Grants.

14.6.1 The United States Hotel and Motel Fire Safety Act of 1990

The Hotel and Motel Fire Safety Act of 1990 (PL101-391) was passed into law by Congress to save lives and protect property by promoting fire and life safety in hotels, motels and other places of public accommodation. PL101-391 states that federally funded meetings and conferences cannot be held in properties that do not comply with the law. PL101-391 is applicable to all places of public accommodation, and requires that such properties are equipped with:

- hard-wired, single-station smoke detectors in each guestroom in accordance with the National Fire Protection Association (NFPA) standard 72;
- an automatic sprinkler system, with a sprinkler head in each guest room in compliance with NFPA standards 13 or 13R. Properties three stories or lower in height are exempt from the sprinkler requirement.

The United States Fire Administration (USFA) is charged with carrying out FEMA's responsibilities with respect to the Hotel and Motel Fire Safety Act of 1990. In addition to compiling, maintaining and publishing the National Master List, USFA is also responsible for taking steps to encourage states to promote the use of automatic sprinkler systems and automatic smoke detection systems.

14.6.2 Guideline on the Inclusion of Underrepresented Populations

Conference grant applicants must address efforts to enhance diversity by increasing the representation of individuals from underrepresented populations in the planning of, implementation of, and participation in

the proposed conference. Underrepresented populations include individuals from nationally underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women (see GPS 11.3.3.4). Plans to enhance diversity must be included in all aspects of the conference, including the selection of the organizing committees, speakers, other invited participants, such as session chairs and panel discussants, and attendees. If plans to enhance diversity are not adequate, NIH will not make an award until the applicant has submitted acceptable documentation of its compliance.

14.6.3 Plans to Promote Safe Environments at Conferences

Consistent with NIH Grants Policy Statement (Section 4.1.2 Civil Rights Protections) and Federal civil rights laws, it is expected that organizers of NIH-supported conferences and scientific meetings take steps to maintain a safe and respectful environment for all attendees by providing an environment free from discrimination and harassment. Conference grant applicants recommended for funding must provide to NIH as part of Just-In-Time materials the "safety plan" that will be communicated to all conference/meeting attendees.

"Safety plans" are required to include the following elements:

- Statement of commitment to provide a safe environment
- Expectations of behavior
    - Including list of behaviors considered harassing (specific emphasis on harassment, sexual, racial, ethnic, or otherwise)
- Instructions on how to confidentially report alleged violations of the expectations of behavior to conference organizers
- Description of how the organizers will assess allegations and the consequences for those who are found to violate the expectations of behavior
- Information explaining that individuals who have questions, concerns or complaints related to harassment are also encouraged to contact the conference organizer or the HHS Office for Civil Rights (OCR)
- Information about how to file a complaint with HHS OCR (see OCR's webpage, Filing a Civil Rights Complaint).
- Information explaining that filing a complaint with the conference organizer is not required before filing a complaint of discrimination with HHS OCR, and that seeking assistance from the conference organizer in no way prohibits filing complaints with HHS OCR.
- Information explaining how individuals can notify NIH about concerns of harassment, including sexual harassment, discrimination, and other forms of inappropriate conduct at NIH-supported conferences (see NIH's Find Help webpage).

R13/U13 applicants recommended for funding must also provide to NIH as part of Just-in-Time materials:

- a description of the strategy that will be used to communicate the Safety Plan to conference attendees and a plan to document allegations and resulting actions.
- information on the steps the organizers will take to ensure a safe and respectful environment for all attendees, free from discrimination and harassment

NIH staff will review all plans and must approve them prior to award. Safety Plans that are deemed incomplete or unsatisfactory will need to be corrected by the applicant and approved by NIH prior to award.

14.7 APPLICATION REVIEW

Applications for conference grants will be reviewed for programmatic relevance and for merit as described in The Peer Review Process in Part I and applicable FOA.

In addition, applications submitted to NIH for support of Scientific Conferences (R13 and U13) are required to include a Conference Grant Application Diversity Plan, as described in 14.6.2.

Reviewers will be asked to evaluate the Conference Grant Application Diversity Plan:

How well does the diversity plan demonstrate efforts to enhance diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups, in the planning and implementation, and participation in the proposed conference? Underrepresented groups include individuals from nationally underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women. For more information, see Notice of NIH's Interest in Diversity; Civil Rights Protections in NIH-Supported Research, Programs, Conferences and Other Activities; and Updated Guidelines on Enhancing Diversity and Creating Safe Environments in Conferences Supported by NIH Grants and Cooperative Agreements.

Reviewers will consider the Conference Grant Application Diversity Plan in determining the scientific and technical merit of the application, and in providing an overall impact score. The Diversity Plan will be evaluated as an additional review criterion and not receive a separate criterion score.

Reviewers will be asked to evaluate PD(s)/PI(s) Personal Statement of the Biographical Sketch:

Is(are) the PD(s)/PI(s) well suited for organizing and fulfilling the goals of this conference, including efforts to enhance diversity? Are the qualifications and past performance of the PD(s)/PI(s) appropriate, and are they well suited for their described roles in the conference? Are the key personnel and selected speakers appropriate and well suited for their described roles in the conference?

14.8 FUNDING

Grants or cooperative agreements may be used to provide conference support. A cooperative agreement may be awarded if the NIH awarding IC determines that it needs to have substantial involvement in the planning and conduct of a conference.

Grant funds may not be used to provide general support for international conferences held in the United States or Canada. Grant funds may be awarded to support only specific aspects of such conferences. An example would be a selected symposium, panel, or workshop, including the costs of planning and travel of U.S. participants.

Awards in support of a single conference will be made for a project period commensurate with the time involved in planning and conducting the conference and post-conference follow-up, usually 1 year. A conference grant made to a permanently sponsoring organization for conferences held annually or biennially on a recurring topic may be awarded for up to a total of 5 years and will be funded annually, based on the availability of funds. Continued funding beyond the first year will be contingent on a report of satisfactory progress submitted in accordance with SNAP instructions. A change in conference focus requires NIH awarding IC prior approval.

14.9 ACKNOWLEDGMENT OF FUNDING SOURCE AND DISCLAIMER

When a conference is funded by an NIH grant or cooperative agreement, recipients must include the following statement on conference materials (including promotional materials, agenda, and internet sites):

> *"Funding for this conference was made possible (in part) by (Insert Grant/Cooperative Agreement #) from (insert name of NIH IC). The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of NIH; nor does mention by trade names, commercial practices, or organizations imply endorsement by the U.S. Government."*

Appropriate use of the NIH or HHS logo on conference materials is of particular importance. Neither logo should be displayed if it would cause confusion as to the source of the conference or give the false appearance of government endorsement. Accordingly, unless specifically authorized by the award, any use of the HHS and/or NIH logo requires prior approval. Unauthorized use of the HHS or NIH name or logo may result in imposition of civil monetary penalties (as provided in 42 CFR Part 1003).

14.10 ALLOWABLE AND UNALLOWABLE COSTS

The following highlights allowable and unallowable costs under conference grants. No costs other than those specified in this subsection as allowable, including any qualifications on their allowability, are permitted under conference grants.

14.10.1 Allowable Costs

In general, consistent with 2 CFR Part 200.432 and 45 CFR Part 75.432, conference hosts/sponsors must exercise discretion and judgment in ensuring that conference costs are appropriate, necessary and managed in a manner that minimizes costs to the Federal award.

Conference Services. Grant funds may be used for necessary recording of proceedings, simultaneous translation, and subsequent transcriptions.

Consultant Services. Grant funds may be used to pay consultant fees, including travel and supporting costs (per diem or, where applicable, subsistence).

Equipment Rental. Grant funds may be used for the rental of necessary equipment.

Federal Employees. See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter.

Meals. When meals are justified by the applicant as an integral and necessary part of a conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, as qualified under Travel below. However, direct charges for meals/food and beverages are unallowable charges to an NIH grant where the primary purpose is to support a scientific meeting/conference.

Publication Costs. When grant funds are awarded to pay for either the entire or partial cost of publication of proceedings or a book or pamphlet, allowable costs include special plates, charts, diagrams, printing, distribution, mailing, postage, and general handling, unless otherwise specified at the time the grant is awarded.

Registration Fees. Grant funds may not be used for registration fees paid by the recipient to other organizations on behalf of attendees. Grant funds may be used to help defray registration costs for some select

conference attendees (for example, women, racial/ethnic minorities, persons with disabilities, other individuals who have been traditionally underrepresented in science, graduate students).

Salaries. In accordance with the policy of the recipient organization, grant funds may be used for all or part of the salaries of professional personnel, clerical assistants, editorial assistants, and other non-professional staff in proportion to the time or effort directly related to the conference.

Speakers Fees. Speakers' fees for services rendered are allowable.

Supplies. Grant funds may be used for the purchase of supplies for the conference if the supplies are received and used during the budget period.

Travel. Funds may be used for the travel of staff, speakers, participants, and attendees, if identified in the application and approved at the time of award. Travel expenses for employees of the recipient organization are governed by the recipient's travel policies, consistently applied regardless of the source of funds.

Any U.S. foreign travel restrictions that are in effect at the time of the award will be followed, such as

- limitations or restrictions on countries to which travel will be supported or
- budgetary or other limitations on availability of funds for foreign travel.

Proposed per diem or subsistence allowances must be reasonable and limited to the days of attendance at the conference plus the actual travel time to reach the conference location by the most direct route. Local mileage costs only may be paid for local participants. Where meals and/or lodgings are furnished without charge or at a nominal cost (e.g., as part of the registration fee), the proposed per diem or subsistence allowance must take this into consideration.

Transportation costs for attendees and participants at the conference may not exceed coach class fares. In all cases, U.S. flag carriers will be used where possible (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Travel in IIA).

In accordance with 2 CFR Part 200.475 and 45 CFR Part 75.474, temporary dependent care costs (as dependent is defined in 26 USC § 152) above and beyond regular dependent care that directly results from travel to conferences is allowable provided that:

1. The costs are a direct result of the individual's travel for the Federal award;
2. The costs are consistent with the non-Federal entity's documented travel policy for all entity travel; and
3. Are only temporary during the travel period.

Travel costs for dependents are unallowable, except for travel of duration of six months or more with prior approval of the HHS awarding agency. However, as indicated in 2 CFR Part 200.432 and 45 CFR Part 75.432, as needed, the costs of identifying, but not providing, locally available dependent-care resources are allowable.

14.10.2 Unallowable Costs

A&R. Not allowable.

Entertainment and Personal Expenses. Costs of amusement, diversion, social activities, ceremonials, and related incidental costs, such as bar charges, tips, personal telephone calls, and laundry charges of participants or guests, are unallowable. However, meals may be allowable as provided under Allowable Costs—Meals above.

Equipment Purchase. Grant funds may not be used for the purchase of equipment.

F&A Costs. Not allowable.

Honoraria. Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or admiration may not be paid from grant funds.

Local Participants' Expenses. With the exception of local mileage as indicated under Allowable Costs—Travel above, grant funds may not be used to pay per diem or expenses for local participants in the conference.

Meals. Direct charges for meals/food and beverages are unallowable charges to an NIH grant where the primary purpose is to support a scientific meeting/conference.

Membership Dues. Not allowable.

Research Patient Care. Not allowable.

Visas and Passports. Not Allowable.

14.11 ADMINISTRATIVE REQUIREMENTS

14.11.1 Intellectual Property: Publications, Copyright, and Public Disclosure

If the recipient publishes material developed in whole or in part with NIH funds, the material may be distributed free of charge. If the recipient organization charges for the material, the sales proceeds are considered program income, and must be accounted for as specified in the NoA and reported on the FFR (see Administrative Requirements—Reporting and Record Retention in this chapter).

Unless otherwise provided in the terms and conditions of the award, the recipient is free to arrange for copyright of any publication resulting from an NIH-supported conference. However, any such copyrighted publication shall be subject to a nonexclusive, irrevocable, royalty-free license to the Federal government to reproduce, translate, publish, and dispose of the material and to authorize others to use the work for government purposes. Copyright does not extend to any materials prepared by Federal employees as part of their official duties.

The recipient is cautioned to remind conference participants that any presentation or discussion constitutes public disclosure of information. Any such public disclosure could seriously impact the degree to which any intellectual property rights could be protected.

14.11.2 Reporting and Record Retention

Upon completion or termination of a grant in support of a conference, recipients are responsible for submitting the final RPPR and the final FFR in accordance with the Closeout provisions described in Administrative Requirements—Closeout in IIA. Submission details of the final FFR and Final Progress Report are described in respective subsections of Closeout.

14.11.2.1 Progress/Final Report

For single conferences, a final report of the conference must be submitted electronically through the eRA Commons, or by paper submission to the NIH DCGP within 120 days after the end of the project period. The report must include the following:

- Grant number
- Title, date, and place of the conference
- Name(s) of the person(s) shown on the application as the conference director or PD/PI(s)
- Name of the organization that conducted the conference
- A list of the individuals, and their organizational affiliations, who participated as speakers or discussants in the formally planned sessions of the meeting
- A summary of topics discussed/conclusions.
- Summary of outcomes of plans to enhance diversity.

Under multiple-year awards, i.e., ones that support more than one conference, NIH requires an annual progress report that contains a description of specific plans for the next budget period, in similar detail and format as for a single conference. The annual progress report must be submitted at least 6 months before the next scheduled conference. The final progress report should be submitted within 120 days after the end of the project period.

With the approval of the NIH awarding IC, copies of proceedings or publications resulting from the conference(s) may be substituted for the final report, provided that they contain the information specified for inclusion in the final report.

14.11.2.2 Federal Financial Report

Electronic submission of the final FFR through PMS is required from the recipient within 120 days after the end of the project period. Records of expenditures and any program income generated must be maintained in accordance with the provisions of 2 CFR Part 200.328 and 45 CFR Part 75.341 (see Administrative Requirements—Monitoring—Record Retention and Access in IIA).

15 CONSORTIUM AGREEMENTS

15.1 GENERAL

This chapter includes the requirements for an applicant/recipient under consortium agreements in which the recipient collaborates with one or more other organizations in carrying out the grant-supported research. The recipient, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the performance of the project, the appropriate expenditure of grant funds by all parties, applicable reporting requirements, and all other obligations of the recipient, as specified in the NIHGPS. In addition, the terms and conditions flow down to subrecipients in accordance with 2 CFR Part 200.101(b)(2) and 45 CFR Part 75.101 - the requirements that apply to the recipient, including the intellectual property requirements in IIA and the program income requirements of the award, also apply to consortium participant(s). Exceptions are noted in this chapter. The recipient is responsible for including the applicable requirements of the NIHGPS in its agreements with collaborating organizations (see Written Agreement in this chapter).

Under grants that include consortium agreements:

- The award will be made to a single recipient with a single PD/PI even though one or more organizations other than the recipient will carry out portions of the planned programmatic activity. When the multiple PD/PI model is used, all PD/PIs are listed on the award regardless of organization affiliation, with the Contact PD/PI so noted.
- The prime recipient must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. This includes being able to provide appropriate oversight of all scientific, programmatic, financial, and administrative matters related to the grant.

Applicants are expected to detail their proposed collaborations as part of the grant application. If the application is approved as submitted, no further approval is required unless, during performance, the recipient plans to undertake additional or alternative collaborations that would constitute a change in the scope of the approved project (see Administrative Requirements—Changes in Project and Budget in IIA). Applicants for STTR grants should follow the specific requirements for research collaboration established for that program (see Grants to For-Profit Organizations chapter).

The following information must be provided to NIH as part of a competing application that proposes consortium arrangements:

- Include all proposed performance sites; those of the applicant organization and the consortium participant(s); and
- Non-modular grant applications must include complete detailed budgets for each consortium participant. Modular grant applications must include an estimate of consortium total costs (direct costs plus F&A costs) each year as part of the budget narrative justification (see Modular Applications and Awards chapter).

For the consortium site, it is appropriate and expected that someone will be designated as the consortium lead investigator responsible for ensuring proper conduct of the project or program at the consortium site. However, this individual must only be assigned the PD/PI role when a multiple PD/PI application is being submitted. Otherwise, this individual should be assigned some other project role in the Senior/Key Personnel section of the application.

The signature (or electronic equivalent) of the AOR/SO on the application signifies that the applicant organization and all proposed consortium participants understand and agree with the following statement:

> "The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy."

NIH may request additional information before award and may place a specific award condition(s) on the award.

15.2 ADMINISTRATIVE AND OTHER REQUIREMENTS

The following highlights several areas within the consortium relationship that the recipient needs to address with consortium organizations receiving subawards under a grant to ensure compliance with NIH requirements. The requirement for a written agreement addressing these and other areas is specified in this section.

Note that most of these requirements only apply to a recipient's consortium relationships with subrecipients. When the relationship is with a vendor that is providing routine goods and services within normal business operations that are ancillary to the operation of the research program, the public policy requirements listed below do not apply. The vendor must also be providing similar goods and services to many different purchasers and provide them in a competitive environment.

15.2.1 Written Agreement

The recipient must enter into a formal written agreement with each consortium participant that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate an efficient collaborative venture. At a minimum, this agreement must include the following:

- Identification of the individual who will serve as the consortium lead investigator and other individuals responsible for the research activity at each consortium participant along with their roles and responsibilities.
- When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but need not be employees. Any consortium agreement must address the unique aspects to these individuals holding the PD/PI role including the requirement for the prime institution to secure and retain all PD/PI signatures for all applications, progress reports, and post-award prior approval requests. Further, such signatures must be made available to NIH or other authorized DHHS or Federal officials upon request. See Multiple Program Director/Principal Investigator Applications and Awards for additional information.
- Procedures for directing and monitoring the research effort.

- Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, procedures for review and approval of expenditures of grant funds at each organization and timing of applicable reporting requirements. This includes provisions on access to core facilities and resources and whether access will be provided as a fee-for-service.
- If different from those of the recipient, a determination of policies to be followed in such areas as travel reimbursement and salaries and fringe benefits (the policies of the consortium participant may be used as long as they meet NIH requirements).
- Terms that establish whether the Financial Conflict of Interest policy of the prime Institution or that of the subrecipient will apply to the subrecipient's Investigators.
- If the subrecipient's Investigators must comply with the prime Institution's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR Part 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the Financial Conflict of Interest policy of the prime Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the prime Institution.
- If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the written agreement shall specify time period(s) for the subrecipient to report all identified Financial Conflicts of Interest to the prime Institution. Such time period(s) shall be sufficient to enable the prime Institution to provide timely FCOI reports, as necessary, to the PHS as required by the regulation.
- Alternatively, if the subrecipient's Investigators must comply with the prime Institution's Financial Conflict of Interest policy, the written agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the prime Institution. Such time period(s) shall be sufficient to enable the prime Institution to comply timely with its review, management, and reporting obligations under the 2011 revised FCOI regulation.
- A provision addressing ownership and disposition of data produced under the consortium agreement. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.
- A provision making NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources in IIA), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the recipient can fulfill its responsibilities to NIH.
- Expectations for authorship and co-authorship on publications.
- Provisions regarding property (other than intellectual property), program income, publications, reporting, and audit necessary for the recipient to fulfill its obligations to NIH.
- Provisions regarding compliance with requirements for a UEI and subrecipient reporting under FFATA (see Recipient Reporting of Subrecipient Data and Executive Compensation Information for FFATA). Note, the recipient must provide the FAIN to all subrecipients to aid in this requirement.

- Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA).

15.2.2 Public Policy Requirements and Objectives

The recipient is responsible for determining whether a consortium participant, including foreign consortium participants under domestic or foreign grants, has filed assurances with NIH that would cover its activities within the consortium and, if not, for ensuring that any required assurances or certifications are submitted to NIH. See Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA for the full statement of these requirements and their applicability to consortium participants.

The recipient is responsible for ensuring that all sites engaged in human subjects research have an appropriate OHRP-approved assurance and IRB approval of the research consistent with 45 CFR Part 46 (see *Guidance on Engagement of Institutions in Human Subjects Research* and for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget in IIA). The list of organizations with approved assurances is available at the OHRP Web site.

The animal welfare requirements that apply to recipients also apply to consortium participants and subprojects. The primary recipient is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. The approval of more than one IACUC is not required if the recipient and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted. If the prime recipient does not have an Assurance and the animal work will be conducted at an institution with an Assurance, the recipient must obtain an Inter-institutional Assurance from OLAW. Under the Inter-institutional Assurance, the recipient and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance. The recipient is further responsible for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements in IIA). See the OLAW web site for a list of domestic organizations and foreign organizations with approved assurances.

15.2.3 Allowable and Unallowable Costs

The recipient must include in consortium agreements the applicable government-wide cost principles and NIH cost policies described in the Cost Considerations chapter in IIA and, as appropriate, requirements related to allowable and unallowable costs in other sections of IIB. For example, a university recipient must flow down the cost principles of 2 CFR Part 200, Appendix IX and 45 CFR Part 75, Appendix IX to a consortium participant that is a hospital. This includes the application of F&A rates in determining consortium budgets and the reimbursement of costs.

Recipients must use an approved federally recognized indirect cost rate negotiated between the subrecipient and the Federal Government. If no such rate exists, the recipient must use either a rate it has negotiated with the subrecipient, including commercial organizations (except for the SBIR/STTR program, as described in 18.5.4.3,or a de minimis indirect cost rate of 10 percent of modified total direct costs (MTDC) if the subrecipient has never received a negotiated indirect cost rate from the Federal Government. Recipients are reminded that F&A reimbursement rates are restricted for certain classes of

awards. If the consortium participant is a Federal organization, direct costs will be limited and no F&A will be provided.. (See Reimbursement of Facilities and Administrative Costs.) For more information on allowable costs to Federal organizations, see Grants to Federal Institutions and Payments to Federal Employees Under Grants.

15.2.4 Approval Authorities

The recipient is responsible for obtaining NIH awarding IC approval for any actions to be undertaken by consortium participants that require prior approval. Recipients may establish requirements for review of consortium participants' activities consistent with those requirements and with any authorities provided to the recipient; however, a recipient may not provide any authority to a consortium participant that the recipient has not been provided under its NIH award.

Regardless of whether there is a change in scope, in all cases, if a recipient (or consortium participant) proposes the transfer of work to a foreign site, awarding IC prior approval is required.

15.2.5 Tangible Personal Property

15.2.5.1 Exempt Property

If the recipient provides exempt property to a consortium participant or authorizes a consortium participant to purchase property that would be considered exempt if acquired by the recipient, the recipient may vest title in the consortium participant upon transfer or purchase or may reserve the right to do so at a later time. The recipient also may establish its own use, disposition, and accountability requirements, provided they are consistent with the NIH right to transfer title (see Administrative Requirements—Management Systems and Procedures—Property Management System Standards—Equipment and Supplies in IIA).

15.2.5.2 Nonexempt Property

If the recipient provides nonexempt property to a consortium participant or authorizes a consortium participant to purchase property that would be considered nonexempt if purchased by the recipient, title to such property must remain with the recipient or be vested in the recipient upon acquisition of the property. The recipient may establish use, accountability, and disposition requirements for the property, provided they are consistent with, and do not impair, the recipient's ability to comply with the requirements of 2 CFR Part 200.311 and 45 CFR Part 75.318, as appropriate.

15.2.6 Audit

The recipient must require consortium participants to comply with the requirements of 2 CFR Part 200, Subpart F and 45 CFR Part 75, Subpart F or 2 CFR Part 200.501 and 45 CFR Part 75.501, as applicable, for audit of NIH grant funds expended by consortium participants. A consortium participant also may be a direct NIH recipient or contractor or may be receiving funds only under the consortium agreement. Regardless, if a non-profit consortium participant meets the 2 CFR Part 200.501 and 45 CFR Part 75.501 threshold criterion of aggregate annual expenditures of $750,000 or more under applicable Federal awards, the recipient must receive a copy of that organization's 2 CFR Part 200.501 and 45 CFR Part 75.501 audit and take appropriate action to resolve any findings that relate to the consortium agreement. The recipient is not responsible for resolving crosscutting findings. If a consortium participant will not reach that expenditure threshold, the recipient is responsible for monitoring the organization's activities to ensure compliance with NIH requirements. The recipient may not require a consortium participant to have an audit and charge the audit costs to NIH grant funds unless required or authorized by 2 CFR Part 200.501 and 45 CFR Part 75.501.

16 GRANTS TO FOREIGN ORGANIZATIONS, INTERNATIONAL ORGANIZATIONS, AND DOMESTIC GRANTS WITH FOREIGN COMPONENTS

16.1 GENERAL

Most of the policies contained in IIA apply to NIH grants made to foreign organizations and international organizations (hereafter "foreign grants"), including the requirements of 2 CFR Part 200 and 45 CFR Part 75 and the cost principles incorporated by reference in those regulations. If an applicant/recipient would be unable to comply with these requirements, the AOR should contact the GMO. Specific exceptions and modifications of IIA requirements for foreign grants, and highlights of other policies, are set forth in this chapter. This chapter also includes policies that apply to domestic grants with a foreign component.

16.2 ELIGIBILITY

In general, foreign organizations and international organizations, including public or private non-profit or commercial organizations, are eligible to apply for research project grants, but are not eligible to submit a modular grant application. International organizations are treated as foreign organizations for the purpose of eligibility. If the Funding Opportunity Announcement (FOA) allows foreign organizations to apply, international organizations may apply. If the FOA does not allow foreign organizations to apply, international organizations may not apply. Foreign organizations and international organizations are not eligible to apply for Kirschstein-NRSA institutional research training grants, program project grants, center grants, resource grants, SBIR/STTR grants, or construction grants. However, some activity codes, such as program project grants (P01), may support projects awarded to a domestic institution with a foreign component. For purposes of this policy, a foreign component is defined as performance of any significant element or segment of the project outside the United States either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include the following:

- The involvement of human subjects or vertebrate animals at a foreign site.
- Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities.
- Any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.

Examples of other grant-related activities that may be significant are:

- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site; or
- receipt of financial support or resources from a foreign entity.

Foreign travel exclusively for consultation is not considered a foreign component.

See Support of Scientific Meetings (Conference Grants) chapter for NIH policy on support of international conferences.

Grants may not be made to individuals in a foreign location (i.e., outside of the United States and its territorial possessions). Occasionally, a Kirschstein-NRSA individual fellowship award is made to a U.S.

citizen or a non-citizen national to study in a foreign organization. (A "non-citizen national" is a person who although not a citizen of the United States owes permanent allegiance to the United States, such as a resident of American Samoa.) See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships for additional information.

16.3 APPLICATION REVIEW

Applications from foreign organizations or international organizations will be evaluated and scored during the initial review process using the standard review criteria. In addition, the following will be assessed as part of the review process and award decision:

- Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.
- Whether the proposed project has specific relevance to the mission and objectives of the IC and has the potential for significantly advancing the health sciences in the United States.

Note, these additional criteria are not applied to applications from domestic organizations with foreign components or applications in response to an FOA requesting applications from foreign organizations only.

Research grant applications from foreign organizations or international organizations may not be funded unless approved by the IC National Advisory Council or Board.

16.4 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

A complete listing of public policy requirements and objectives and their applicability to foreign grants is included in Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA. Several of the public policy requirements and objectives are highlighted below:

- ***Research Misconduct.*** The research misconduct requirements included in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Research Misconduct apply to foreign grants.
- ***Animal Welfare.*** The animal welfare requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Animal Welfare apply to foreign grants, regardless of the requirements of the home country.
- ***Human Subjects.*** The human subjects requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Human Subjects Protections, including the requirement for an assurance pursuant to 45 CFR Part 46, apply to foreign grants and foreign consortium participants under domestic or foreign grants.
- ***Financial Conflict of Interest.*** The financial conflict of interest requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates— Financial Conflict of Interest apply to foreign grants.
- ***Inclusiveness in Research Design.*** Foreign grants are subject to the requirements for inclusion of women, minorities, and individuals across the lifespan in research design as specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Inclusion of Children as Subjects in Clinical Research and Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender and Racial and Ethnic Participation.

- ***Civil Rights.*** The civil rights requirements specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Civil Rights do not apply to foreign grants.
- ***Lobbying.*** The requirements of Public Policy Requirements, Objectives, and Other Appropriation Mandates—Lobbying Prohibition, including disclosure reporting, apply to foreign grants.
- ***Debt.*** Foreign applicants are required to provide a certification of nondelinquency on debts owed to the United States as specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Nondelinquency on Federal Debt.
- ***Debarment and Suspension.*** Applicants/recipients that are foreign governments or governmental entities, public international organizations, or foreign-government-owned or -controlled (in whole or in part) entities are not subject to the debarment or suspension certification requirement or to debarment or suspension under 2 CFR Part 376. All other foreign organizations and international organizations are subject to these requirements. See Public Policy Requirements, Objectives, and Other Appropriation Mandates—Debarment and Suspension for additional information on this requirement.
- ***Drug-Free Workplace.*** Foreign applicants and recipients may be exempted from the drug-free workplace requirements of 2 CFR Part 182 based on a documented finding by the NIH awarding IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government. See Public Policy Requirements, Objectives, and Other Appropriation Mandates—Drug-Free Workplace for additional information on this requirement.

16.5 FUNDING AND PAYMENT

The application budget, requests for funds, and financial reports (see Reporting and Record Retention in this chapter) must be stated in U.S. dollars. Cost increases for fluctuations in exchange rates are allowable costs subject to the availability of funding, as determined by the awarding IC. Prior approval of exchange rate fluctuations is required only when the charge results in the need of additional Federal funding, or the increased costs result in the need to significantly reduce the scope of the project. The non-Federal entity is required to make reviews of local currency gains to determine the need for additional federal funding before the expiration date of the Federal award. Subsequent adjustments for currency increases may be allowable only when the non-Federal entity provides the awarding IC with adequate source documentation from a commonly used source in effect at the time the expense was made, and to the extent that sufficient Federal funds are available.

Awards to foreign and international organizations are paid through PMS. PMS is operated by the PSC in accordance with Department of the Treasury and OMB requirements as implemented by 2 CFR Part 200.305 and 45 CFR Part 75.305. These requirements are intended to minimize the time elapsing between the transfer of funds from the U.S. Federal government and disbursed by the recipient. Therefore, although the grant may be financed by advance payments, the intent is that recipients draw funds on an as-needed basis – specifically, no more than 3 days before the funds are needed.

Operational guidance for recipients is provided through a training CD from PSC. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds should be directed to PSC/PMS (see Part III).

The funding and payment information outlined in this subsection applies when the foreign organization is the recipient organization. When a foreign component participates in a consortium arrangement, the funding and payment information should be reflected in the formal written agreement. Recipients are required to maintain grant funds in an interest bearing account; however, interest earned in excess of

$500 per year in the aggregate on advances of Federal funds must be returned in U.S. dollars by reimbursement check to OFM, and reflected on the annual FFR.

For more information on payment, see Payment Chapter.

Any questions regarding payments to foreign recipients may be addressed to the Grants Management Specialist noted on the NoA or PSC (see Part III for address and telephone and fax numbers).

16.6 ALLOWABLE AND UNALLOWABLE COSTS

The cost principles that apply to foreign organizations depend on the type of organization, i.e., for a university 2 CFR Part 200, Subpart E—Cost Principles would apply, with the following exceptions:

- ***Major A&R.*** Unallowable under foreign grants and domestic grants with foreign components.
- ***Minor A&R.*** Generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations. Minor A&R costs may be included and justified in any detailed budget of a competing application. Further, rebudgeting of active grants to accommodate minor A&R is also allowable; however, this does require NIH prior approval of the GMO. Additional information may be required (see Administrative Requirements—Alteration and Renovation Projects under Non-construction Grants in IIB).
- ***F&A Costs.*** With the exception of the American University of Beirut and the World Health Organization, which are eligible for full F&A cost reimbursement, F&A costs under grants to foreign and international organizations will be funded at a fixed rate of 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. Some examples of NIH compliance requirements are the protection of human subjects (including the required education in the protection of human research participants), animal welfare, invention reporting, other post-award reporting requirements, financial conflict of interest and research misconduct. Note, these are just a few representative examples of compliance requirement; this list is not all inclusive. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. NIH will not support the acquisition of or provide for depreciation on any capital expenses (facilities) or the normal general operations of foreign and international organizations. Therefore, these expenses may not be requested as a direct cost; however, equipment is an allowable direct cost. *Other items normally treated as F&A costs (e.g., rent) may be requested as direct costs and will be evaluated by NIH for allowability.*
- ***Patient Care Costs.*** Patient care costs are provided only in exceptional circumstances.
- Travel Visas (including short-term). Generally, allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual. Visa costs may also be allowable when identified in specific FOAs or when within the scope of an approved research project..See 7.9.1 Recruiting Costs and Travel Visas.

16.7 ADMINISTRATIVE REQUIREMENTS

For SNAP awards to foreign organizations recipients are required to submit FFR expenditure data at the end of the competitive segment only. NIH staff now monitors financial aspects of these grants through

subaccounts in PMS. For all non-SNAP awards to foreign organizations recipients are required to submit FFR expenditure data annually.

16.7.1 Changes in Project and Budget

Foreign grants are subject to NIH Standard Terms of award, see Administrative Requirements—NIH Standard Terms of Award in IIA. Inclusion in SNAP is at the discretion of the NIH awarding IC and will be specified in the NoA.

16.7.2 Change in Scope

A change in the performance site within a foreign country or the addition of a performance site in a country other than that specified in the approved application requires NIH awarding IC prior approval. The transfer of work by a domestic recipient to a foreign component also requires awarding IC prior approval.

16.7.3 Change of Recipient Organization

A change of recipient organization that involves the transfer of a grant to or between foreign organizations or international organizations requires approval of the NIH awarding IC and its National Advisory Council or Board. NIH awarding IC approval also is required for the transfer of a grant from a foreign organization to a domestic organization. Recipients adding or changing a foreign performance site within a funded grant award must obtain approval from the GMO before work can be performed at the added or changed foreign site.

16.7.4 Audit

Foreign recipients are subject to the same audit requirements as commercial organizations (specified 2 CFR Part 200.501 and 45 CFR Part 75.501 and in the in the Grants to For-Profit Organizations chapter).

16.7.5 Reporting and Record Retention

For SNAP awards, foreign recipients submit FFR expenditure data at the end of the competitive segment only. Awards are administered in PMS using subaccounts and payments will be specific to each grant at the time the recipient draws funds.

The FFR expenditure data must be submitted electronically through PMS and must be submitted in U.S. dollars and in English. The currency rate in effect at the time the funds are drawn down from PMS should be used in preparing the FFR. For the final FFR, NIH requires recipients to reimburse the U.S. government for funds not spent. Mail reimbursement checks in U.S. dollars to the OFM.

All foreign recipients, contractors, consortium participants, and/or subcontractors must comply with Bayh-Dole invention reporting requirements. Regarding intellectual property, foreign recipients have the same rights and obligations regarding invention ownership as U.S. recipients. (See Interagency Edison for more information.)

Record retention requirements are the same as those for domestic recipients.

17 GRANTS TO FEDERAL INSTITUTIONS AND PAYMENTS TO FEDERAL EMPLOYEES UNDER GRANTS

17.1 GENERAL

NIH may award grants to Federal entities. Although the activity under these grants will take place in a research environment, certain terms and conditions vary from those included in IIA due to the recipient's status as a Federal institution. This chapter specifies those differences as well as differences in treatment among different Federal institutions. This chapter does not apply to Federally Funded Research and Development Centers (also known as Government Owned Contract Operated facilities) since the recipient institution is the institution operating the facility. In addition, this chapter addresses the policies that apply to payments to (or on behalf of) Federal employees under grants, including grants awarded to organizations other than Federal institutions.

17.2 ELIGIBILITY

In general, Federal institutions are eligible to apply for NIH grants, including research project grants. Specific eligibility will be stated in each FOA. Federal institutions also must meet the eligibility requirements of the grant program from which support is sought. PHS organizational segments, other than IHS hospitals, may receive NIH grant support under exceptional circumstances only. Such circumstances may include situations where a project cannot be supported within the mission of the applicant PHS agency or organizational segment, the activity cannot be performed elsewhere, or its nonpursuit would have an adverse impact or potentially important effect on the NIH mission, and NIH determines a grant is the appropriate means of carrying out the activity. However, NIH may not award a grant to an NIH component.

Although the performance site may be at a level lower than the agency or department level of the Federal institution, when an award is made to an eligible Federal institution, the Federal agency or department will be the recipient of record and must assume responsibility for the project. A Federal institution also must ensure that its own authorizing legislation will allow it to receive NIH grants and to be able to comply with the award terms and conditions.

A document that assures both the assumption of responsibility and authority to receive a grant must accompany each new and competing continuation application. The assurance must be signed by the head of the responsible Federal department or independent agency or a designee who reports directly to the department or agency head. (In the case of the DoD, the Departments of the Army, Navy, and Air Force are considered the Federal department, and their Secretaries the responsible Department head.) This assurance is in addition to those made by the AOR's signature on the face page of the application. The assurance requirement does not apply to VAMCs, Bureau of Prisons' (Department of Justice) hospitals, IHS hospitals, or other PHS organizational segments.

17.3 VA-UNIVERSITY AFFILIATIONS

Investigators with joint appointments at a VAMC (VA hospital) and an affiliated university must have a valid MOU that specifies (at both the university and the VAMC) the title of the investigator's appointment, distribution of compensation, the responsibilities of the proposed investigator, and the percentage of effort available for research at each institution. The MOU must be signed by the appropriate officials of the recipient and the VAMC, and must be updated with each significant change of the investigator's

responsibilities or distribution of effort and, without a significant change, not less than annually. The joint VA/university appointment of the investigator constitutes 100 percent of their total professional responsibilities. However, NIH will recognize such a joint appointment only when a university and an affiliated VA hospital are the parties involved.

A grant application from a university may request the university's share of an investigator's salary in proportion to the effort devoted to the research project. The institutional base salary as contained in the individual's university appointment determines the base for computing that request.

The signature of the AOR of the submitting university on an application to NIH that includes such an arrangement certifies that

- the individual whose salary is included in the application serves under a joint appointment documented in a formal MOU between the university and the VA, and
- there is no possibility of dual compensation for the same work or of an actual or apparent conflict of interest.

Under the above-described arrangement, there is no involvement of a VA-affiliated non-profit research corporation, which is eligible to apply for and receive NIH grants in its own right as a non-profit organization. The limitations on the payment of Federal salaries apply (see Allowable and Unallowable Costs in this chapter).

17.4 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

The requirements concerning disclosure of financial conflicts of interest (see Public Policy Requirements, Objectives, and Other Appropriation Mandates—Financial Conflict of Interest in IIA) do not apply to Federal employees and/or Federal agencies. All other Public Policy Requirements described in IIA apply to Federal recipients.

17.5 PAYMENT

The NIH Office of Financial Management (OFM) will pay grants and cooperative agreements to Federal departments and agencies through the Interagency Payment and Collection method (IPAC). Upon receipt of an NIH award, in order to be reimbursed, Federal recipient institutions may send IPACs to NIH Agency Location Code (ALC) 75080031 for payment.

17.6 ALLOWABLE AND UNALLOWABLE COSTS

Allowable and unallowable costs under grants to Federal institutions will be determined by the established policies of the institution, consistently applied to both its own activities and to grant-supported activities, and the requirements of this subsection. In the absence of a governing organizational policy, the cost principles in 2 CFR Part 200, Subpart E and 45 CFR Part 75, Subpart E will apply.

Salaries. See Federal (U.S. Government) Employees below.

Institutional Allowances Under Kirschstein-NRSA Individual Fellowships. Institutional allowances may be requested by Federal institutions sponsoring a predoctoral or postdoctoral fellow.

F&A Costs. F&A costs will not be provided to Federal institutions.

Federal (U.S. Government) Employees. Whether or not costs will be charged to the grant, when a Federal employee will be involved in an NIH grant-supported activity in any capacity other than as an employee working on a grant to a Federal institution, or a study subject, specified conditions apply as provided in this subsection. The limitations in this subsection do not apply to individuals that are

classified as special government employees because of service on advisory groups or as a result of a formal consulting arrangement with a Federal agency. (See the HHS Standards of Conduct at 45 CFR Part 73, Subpart J for additional guidance.) The Federal employee should consult with their agency ethics officials to determine whether outside activity approval is required by their employing agency.

Only four types of costs—consultant fees, subject costs, salary or fringe benefits, and travel costs—can be charged to NIH grants on behalf of Federal employees, whether by a recipient or a consortium participant, and under the conditions specified only. Applicants/recipients should advise any Federal employee with whom these types of arrangements may be made to consult with their employing agency concerning their ability to participate and to meet the required conditions for payment. The applicant organization must submit, as part of the grant application, any letters or documentation specified below, and that documentation must be deemed acceptable by the GMO before the Federal employee's involvement in the project.

Consultant Fees. Consultant fees are allowable only for medical personnel of the Uniformed Services of the United States (excluding PHS Commissioned Officers) and when all of the following conditions are present:

- The employees are providing the kind and extent of medical services approved in the grant award.
- Adequate numbers of qualified civilian personnel are not available to provide these services, and eligible Federal medical personnel are hired only in addition to those qualified civilian medical personnel, if any, who are available.
- The applicant organization provides prior written authorization from the proposed consultant's commanding officer that they are authorized to work on the grant-supported activity during non-duty hours or while on authorized leave, and can be paid for their efforts.

Outpatient or Subject Costs. These costs are allowable when the federal employee is an outpatient or subject under study in connection with grant-supported activities.

Salary or Fringe Benefits. In most circumstances no salary or fringe benefit payments may be made from NIH grant funds to support Federal employees. While the level of effort required for the research project must be allowed by the employing agency as part of the individuals' official duties, salary and fringe benefit costs associated with an individual participating in an official capacity as a career, career-conditional, or other Federal employees (civilian or uniformed services) are not allowable. Salary and fringe benefits payments may only be made when prior approval is obtained from an authorized official of the employee's agency and the employee is one of the following:

- A temporary employee specifically hired to assist in the performance of an NIH grant.
- A PHS Commissioned Officer or a civil service employee carrying out duties for which specific statutory authorization exists permitting direct Federal assistance in lieu of cash under the grant, or where the government is reimbursed for services rendered subject to restrictions applicable to such personnel, including the applicable Federal standards of conduct (for HHS, 45 CFR Part 73).

- A PHS Commissioned Officer on LWOP if the
    - recipient has obtained written prior approval from the NIH awarding IC;
    - total amount of salary paid from NIH grant funds is proportional to the time devoted to the project and does not exceed the total annual amount of pay and allowances the individual would have received if not in LWOP status; and
    - parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.
- A civil service employee participating in a grant to a non-Federal organization and all of the following conditions are met:
    - The individual is participating as part of an approved IPA assignment in a role other than as PD/PI. IPA assignments generally do not exceed 2 years and may not exceed 4 years of continuous duration (5 U.S.C. 3372). Based on this statutory time restriction, the involvement of the civil service employee should be limited in scope. Therefore, the proposed PD/PI for an NIH grant may not be participating through an IPA. On a case-by-case basis, the NIH awarding IC may determine that certain other senior/key personnel on the project are sufficiently critical to its long-term success that participation through an IPA is not appropriate. Note, a Federal agency may not send or receive on assignment an employee who has served under the mobility authority for 4 continuous years without at least a 12-month return to duty with the organization from which originally assigned (5 CFR Part 334).
    - Before making any payment from NIH grant funds to such an employee, the recipient must certify that the employee is on an IPA assignment and must provide adequate documentation, as determined by NIH, of the IPA assignment and information about its nature and duration.
    - The level of effort required for the research project must be allowed by the employing agency as part of the individual's official duties. Salary payments from NIH grant funds must be proportional to the time an individual devotes to the grant-supported project. The total salary support may not exceed the normal level of compensation from Federal salary if the individual were not participating in the grant.
    - The parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.
- A part-time VA employee at VANPCs for which NIH grant funds are used to pay the differential between the individual's VA part-time salary and the salary level for a full-time VANPC commitment in proportion to the level of effort devoted to the project. Compensation must be in accordance with the established policies and salary structure of the VANPC and the total number of VA and VANPC hours should not exceed a full time position. Therefore, if the PD/PI has a part-time appointment with the VANPC, an appropriate portion of the individual's salary that would otherwise be supported by the non-profit VANPC may be charged to the NIH grant. The work paid for by the VANPC must not be for the same project paid for by VA time for VA salary in accordance with the VA policy set forth in the VHA Handbook 1200.17.

Travel Costs. Travel costs are allowable if the employee is

- working under a grant to a Federal institution;
- performing allowable reimbursable services as specified under Salary or Fringe Benefits immediately above; or
- attending an NIH grant-supported conference
    - during non-duty hours,
    - while in a preexisting LWOP status or one that continues beyond the conference, or
    - while on detail to a State or local government, Institution of Higher Education (IHE), or other non-profit organization.

Such payments must be made in accordance with established organizational policy and consistently applied regardless of the source of funds, and the parties concerned must take reasonable steps to ensure that there is no actual or apparent conflict of interest.

17.7 ADMINISTRATIVE REQUIREMENTS

17.7.1 Equipment Accountability

NIH will consider all nonexpendable personal property acquired under a grant awarded to a Federal institution as exempt (see 2 CFR Part 200.312 and 45 CFR Part 75.319) for purposes of determining the accountability requirements of 2 CFR Part 200.313 and 45 CFR Part 75.320. However, NIH has the right to require transfer of equipment, including title, to NIH or an eligible third party named by the NIH awarding IC under the conditions specified in 2 CFR Part 200.313 and 45 CFR Part 75.320.

17.7.2 Procurement Requirements

Procurement under grants to Federal institutions is governed by the FAR and the recipient agency's FAR supplement.

17.7.3 Intellectual Property

Inventions resulting from grants supporting the activities of Federal employees under grants to Federal institutions must be reported simultaneously to NIH and to the employing agency under the terms of EO 10096, as amended, and are subject to the government assignment of rights in invention of government employee requirements of 37 CFR Part 401. (See http://iEdison.gov for reporting requirements.) Any resulting patent applications and patents must identify the NIH award, consistent with the language of 37 CFR Part 401.14(f)(4). In cases where the VA is involved with the invention but is not the grant recipient, and the recipient institution chooses not to elect title or pursue practical application of an invention, the recipient must note VA's involvement on its notice to NIH and provide a courtesy copy of the NIH notification to the appropriate VA office. NIH will notify the recipient and the VA whether NIH has an interest in taking title and/or continuing the pursuit of practical application of the invention.

17.7.4 Reporting Requirements

Federal institutions must electronically submit annual expenditure FFRs regardless of whether the award is subject to SNAP.

18 GRANTS TO FOR-PROFIT ORGANIZATIONS

18.1 GENERAL

Some of the terms and conditions for grants to commercial (commercial) organizations vary from the standard terms and conditions included in IIA. In addition, the terms and conditions of the SBIR and STTR programs vary from those otherwise applicable to commercial organizations. This chapter addresses separately the policies applicable to commercial organizations generally, and those that apply to SBIR and STTR awards specifically. It also highlights several policies in IIA that apply equally to commercial and non-profit recipients. If an exception is not stated below or in the NoA, the terms and conditions specified in IIA apply, including requirements for the protection of human subjects and animal welfare.

18.2 ELIGIBILITY

Commercial organizations are eligible to apply under all NIH programs and support mechanisms unless specifically excluded by statute.

18.3 ALLOWABLE AND UNALLOWABLE COSTS

18.3.1 Cost Principles

There are no cost principles specifically applicable to grants to commercial organizations. Therefore, the cost principles for commercial organizations set forth in the FAR (48 CFR Part 31.2) generally are used to determine allowable costs under NIH grants to commercial organizations. As provided in those costs principles, allowable travel costs may not exceed those established by the FTR. The cost principles in 2 CFR Part 200, Appendix IX, Hospital Cost Prin-cipals, are used to determine allowable costs under NIH grants to proprietary hospitals.

18.3.2 Independent Research and Development Costs

As provided in 45 CFR Part 75.476, NIH does not allow commercial organizations to be reimbursed for IR&D (self-sponsored) costs.

18.3.3 Facilities and Administrative Costs (Indirect Costs)

F&A costs, including de minimis costs when appropriate, are allowable under awards to commercial organizations. See "Reimbursement of Facilities and Administrative Costs" on page IIA-66.

18.3.4 Profit or Fee

Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a commercial organization, whether as a recipient or as a consortium participant. A profit or fee under a grant is not a cost, but is an amount in excess of actual allowable direct and F&A costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an NIH grant providing routine goods or services to the recipient.

18.4 ADMINISTRATIVE REQUIREMENTS

commercial organizations generally are subject to the same administrative requirements as non-profit organizations, including those relating to personal property title and management. Exceptions to or elaboration of those requirements for commercial organizations are indicated below.

18.4.1 Equipment Accountability

commercial recipients of NIH grants are nonexempt and subject to the requirements in 2 CFR Part 200.313 and 45 CFR Part 75.320, as well as the conditions set forth in Administrative Requirements—Management Systems and Procedures—Property Management System Standards and Administrative Requirements—Management Systems and Procedures—Procurement Systems Standards and Requirements in IIA. Under the conditions specified in 2 CFR Part 200.313 and 45 CFR Part 75.320, commercial recipients are permitted to retain title to equipment purchased under a research grant though NIH reserves the right to order the transfer of equipment, including title, to NIH or an eligible third party named by the NIH awarding office when such third party is otherwise eligible under existing statutes. In addition, commercial recipients must not use equipment acquired with NIH funds to provide services to non-Federal organizations for a fee to compete unfairly with private companies that provide equivalent services, unless the terms and conditions of the award provide otherwise, and any user charges shall be treated as program income and must be reported on the FFR. Conditions for the sale of equipment are specified at Administrative Requirements—Management Systems and Procedures—Sale of Real Property, Equipment, and Supplies in IIA.

18.4.2 Intellectual Property

Intellectual property requirements set forth in 37 CFR 401 apply to commercial organizations, whether small businesses or large businesses. However, invention reporting requirements for commercial organizations differ somewhat from those for non-profit organizations. When the recipient is a commercial organization, assignment of invention rights to a third party does not require NIH approval, but ongoing reporting remains a requirement for each invention. (See Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources in IIA.) Additional information about the requirements of 37 CFR 401 may be obtained from the Division of Extramural Inventions and Technology Resources, OPERA, NIH (see Part III for address and telephone number).

To the extent authorized by law, the Federal government will not make public any information disclosing a Federal government-supported invention.

18.4.3 Program Income

Consistent with NIH Standard Terms of Award, commercial recipients, including those under the SBIR/STTR programs, are subject to the additive alternative for the use of program income described in Administrative Requirements—Management Systems and Procedures—Program Income in IIA.

18.4.4 Operating Authorities

Awards to commercial organizations are subject to NIH Standard Terms of Award; however, some mechanisms do not allow automatic carryover of unobligated balances of funds. Under those mechanisms, the NIH awarding IC will specify the disposition of the reported unobligated balance in the NoA. (See Administrative Requirements—Changes in Project and Budget in IIA).

18.4.5 Audit

The requirements for non-Federal audits of commercial organizations are specified in 2 CFR Part 200.501 and 45 CFR Part 75.501. commercial organizations are subject to requirements for non-Federal audits. A commercial organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $750,000 or more under one or more HHS award (as a direct recipient or consortium participant). Audits must be completed and submitted to the Department of Health and Human Services, Audit Resolution Division within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier. The address is found in Part III.

Commercial organizations expending less than $750,000 a year are not required to have an annual audit for that year but must make their grant-related records available to NIH or other designated officials for review or audit.

18.4.6 Labor Distribution Requirements for For-Profit Organizations

Salary and wage amounts charged to grant-supported projects for personal services must be based on an adequate labor distribution system that distributes payroll costs in accordance with generally accepted practices of like organizations. Standards for labor distribution systems are contained in the applicable cost principles (other than those for commercial organizations).

NIH requires commercial organizations to conform with industry standards to support salary and wage charges to NIH grants. Therefore, unless an alternate system is approved by the GMO, the recipient must maintain a time and-effort reporting system for both professional and other-than-professional staff reflecting daily after-the-fact reporting of hours expended on individual projects or indirect activities. The system must record both hours worked and hours absent. This information must be certified by an AOR no less frequently than every pay period.

18.5 SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAMS

NIH is required by statute to reserve a portion of its annual extramural budget for projects under the SBIR and STTR programs. These programs primarily are intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded R&D.

The SBIR and STTR programs were reauthorized and modified by Congress under P.L. 114-328, Section 1834, and P.L. 115-232. These authorities modified several aspects of the programs, including small business eligibility requirements. Updates on reauthorization implementation will be posted on NIH's SBIR web page. NIH will issue Guide Notice/s to advise the community about the impact on NIH's SBIR and STTR programs.

The SBIR and STTR programs are phased programs:

Phase I. The objective of this phase is to establish the technical merit and feasibility of proposed research or R&D efforts and to determine the quality of performance of the prime applicant (small business concern or SBC) before providing further Federal support in Phase II.

Phase II. The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding will be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. Unless submitted as a Fast-Track application (see here), Phase II STTR applications may be submitted only after the Phase I award is made.

For small businesses that have already demonstrated scientific and technical merit and feasibility but have not received a Phase I SBIR or STTR for that project, NIH can issue a SBIR Direct to Phase II award. The NIH SBIR Direct to Phase II will accept SBIR Phase II applications regardless of the funding source for the proof of principle work on which the proposed Phase II research is based.

Small business concerns (SBCs) eligible to submit Phase II applications for projects that were supported with a Phase I SBIR or STTR award from NIH or any other agency are expected to submit Phase II application through SBIR/STTR solicitations as "Renewal" applications based on the awarded Phase I SBIR or STTR project. Only one Phase II award may be made for a specific project supported by a Phase I award. NIH policies regarding overlapping applications (Sec. 2.3.7.4) still apply. A Phase II recipient may receive one additional, sequential Phase II award (called NIH Phase IIB) to continue the work of an initial Phase II award.

For small businesses that have received a Phase I SBIR or STTR, NIH expects non Fast-Track Phase II applications to be submitted within the first six receipt dates following expiration of the Phase I budget period, i.e., normally 2 years beyond the completion date of the Phase I award.

Some NIH ICs offer Phase II SBIR / STTR recipients the opportunity to apply for Phase IIB Competing Renewal awards. These are available for those projects that require extraordinary time and effort, including those requiring regulatory approval or developing complex instrumentation, clinical research tools, and behavioral interventions. NIH ICs accept phase IIB applications through the Omnibus SBIR/STTR Grant Solicitation or other specific funding opportunity announcements. Only those small business concerns who have been awarded a Phase II are eligible to apply for a Phase IIB Competing Renewal award. Prospective applicants are strongly encouraged to contact NIH staff prior to submission. Additional requirements and instructions (e.g., submission of a letter of intent) are available in the specific IC research topics section and in the specific IC Program Funding Opportunity Announcements.

Some NIH ICs offer Phase II SBIR/STTR recipients the opportunity to apply for Commercialization Readiness Pilot (CRP) Program. The goal of the CRP is to facilitate the transition of previously funded SBIR/STTR Phase I/IIB projects to the commercialization stage by providing additional support for later stage research and development (R&D) and product development not typically supported through Phase II or Phase IIB grants or contracts.

There are two major differences between the SBIR and STTR programs:

- Primary Employment: Under the SBIR Program, the Project Director/Principal Investigator (PD/PI) must have their primary employment with the small business concern at the time of award and for the duration of the project period. However, under the STTR Program the PD/PI may have their primary employment with either the small business concern or the collaborating research institution. On an STTR project, the PD/PI must devote at least 10 percent of their time to the STTR project. For purposes of the SBIR and STTR Programs, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the recipient.
- Partnering Research Institution: The STTR program *requires* for both phases I and II that the SBC formally partner with a single, non-profit research institution. At least 40 percent of the STTR research project is to be conducted by the SBC and at least 30 percent of the work is to be conducted by the single, "partnering" research institution through a formal, cooperative arrangement. Such organizations include universities, non-profit hospitals, and other non-profit research organizations as well as Federally Funded Research and Development Centers. STTR grants are awarded to the SBC, which will receive all of the funding for the project and disburse the appropriate funding to the research institution. The SBIR program allows subcontracting, it does not require it so the SBC may conduct the entire SBIR project without outside collaboration.

SBIR/STTR program policy allows the following:

- Phase I STTR Recipients may apply for NIH SBIR or STTR Phase II.
- Phase I SBIR Recipients may apply for NIH SBIR or STTR Phase II.
- Phase II STTR Recipients may apply for NIH SBIR Phase IIB or STTR Phase IIB or CRP.
- Phase II SBIR Recipients may apply for NIH SBIR Phase IIB or STTR Phase IIB or CRP.
- Phase IIB STTR Recipients may apply for the CRP Program.
- Phase IIB SBIR Recipients may apply for the CRP Program.

Applicants may 'switch' programs to any active and open NIH SBIR or STTR solicitation, including the Omnibus and any targeted funding opportunity.

Note: There are distinct policies for each program—SBIR and STTR—and each phase within these programs. Applicants that 'switch' programs must comply with the policies for the program and FOA to which they submit the application. See 18.5.5.4 SBIR Life Cycle Certification and Sec. 18.5.5.5 STTR Life Cycle Certification for further information.

18.5.1 NIH Fast-Track Application Process

The NIH Fast-Track application process expedites award decisions and funding of SBIR and STTR Phase II applications for scientifically meritorious projects that have a high potential for commercialization. The Fast-Track process allows Phase I and Phase II grant applications to be submitted and reviewed together. Fast-Track applications receive a single rating. Before submitting applications for Fast-Track review, applicants are strongly encouraged to consult with cognizant NIH program staff to assure Fast-Track is appropriate. For additional information on the submission of Fast-Track applications, see the SF424 (R&R) SBIR/STTR Application Guide.

18.5.2 Eligibility

Only United States small business concerns (SBCs) are eligible to submit SBIR and STTR applications. A small business concern is one that, at the time of award for both Phase I and Phase II SBIR awards, meets all the following criteria. If it appears that an applicant organization does not meet the eligibility requirements, NIH will request a size determination by the SBA. If eligibility is unclear, NIH will not make an SBIR or STTR award until the SBA provides a determination.

1. SBIR Eligibility Requirements

a. Organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials;

b. In the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there must be less than 50 percent participation by foreign business entities in the joint venture;

c.

i. Be a concern which is more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens of the United States), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States), an Indian tribe, ANC (Alaska Native Corporation) or NHO (Native Hawaiian Organization) (or a wholly owned business entity of such tribe, ANC or NHO), or any combination of these; OR

ii. Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these. No single venture capital operating company, hedge fund, or private equity firm may own more than 50% of the concern; OR

iii. Be a joint venture in which each entity to the joint venture must meet the requirements set forth in paragraph c(i) or c(ii) of this section. A joint venture that includes one or more concerns that meet the requirements of paragraph (ii) of this section must comply with § 121.705(b) concerning registration and application requirements.

d. Has, including its affiliates, not more than 500 employees and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

2. STTR Eligibility Requirements

a. Organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials;

b. In the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there must be less than 50 percent participation by foreign business entities in the joint venture;

c.

i. Be a concern which is more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens of the United States), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States), an Indian tribe, ANC (Alaska Native Corporation) or NHO (Native Hawaiian Organization) (or a wholly owned business entity of such tribe, ANC or NHO), or any combination of these; OR

ii. Be a joint venture in which each entity to the joint venture must meet the requirements set forth in paragraph c(i) of this section.

d. Has, including its affiliates, not more than 500 employees and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR Part 121.3-2(a). The term "number of employees" is defined in 13 CFR Part 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration Size District Office.

18.5.2.1 Place of Performance

For both Phase I and Phase II SBIR/STTR awards, the research or R&D project activity must be performed in its entirety in the United States. (The United States is defined as the 50 States, the territories and possessions of the United States, the Commonwealth of Puerto Rico, the Federated States of Micronesia, the Republic of Palau, the Republic of the Marshall Islands, and the District of Columbia.)

In those rare instances where the study design requires use of a foreign site (e.g., to conduct testing of specific patient populations or if a supply or material is not available in the United States), the investigator must provide compelling scientific justification in the application that it is not possible to perform the R&D project activity in the United States and for the need / use of a foreign site. NIH will consider these instances on a case-by-case basis, and they should be discussed with cognizant NIH staff before submitting an application. Approval will not be considered unless the application is being considered for an award and applicants may be required to provide additional justification. IC GMOs have the authority to approve these waiver requests. Whether the request is approved or disapproved, it will be explicitly addressed in the NoA if an award is made. Whenever possible, work outside the United States, which is necessary to the completion of the project, should be supported by funding other than SBIR / STTR.

18.5.2.2 Change in Organization Size & Change of Recipient Institution Actions

Applicant organization eligibility is determined at the time of the initial SBIR / STTR award. In the case where an organization grows to be other than small, NIH may exercise its ability to perform a review to determine whether the SBIR / STTR award will continue. At the time of continuation award, the size and eligibility status of the small business organization for the SBIR/STTR program will be reassessed and no new or continuation awards will be issued to ineligible organizations.

In alignment with NIH GPS Section 8.1.2.8 Change in Recipient Organizational Status and NIH GPS Section 8.1.3 Requests for Prior Approval, recipients must give NIH advance notice for legal actions such as merger, acquisition, and successor-in-interest as soon as possible, but no later than 30 days before the proposed change, so that NIH can determine if the organization will continue to meet the SBIR /STTR program eligibility requirements.

In the case of a legal action such as a merger, acquisition, or successor-in-interest action for a small business organization, the transferee organization must recertify its small business status in order for NIH to revise currently active SBIR / STTR awards to reflect the transferee as the recipient of record. However, if the legal action changes the organization size so that they cannot recertify its small business status, rendering it ineligible for the SBIR / STTR programs, existing SBIR / STTR awards cannot be awarded additional funds, including noncompeting continuation awards and supplements to awards. NIH will not issue change in organization status award to the transferee organization for any SBIR/STTR awards, as the organization is ineligible for the SBIR/STTR program. Additionally, all existing SBIR/STTR awards issued to the original recipient will be terminated.

When there is a desire to transfer an SBIR/STTR grant to a different organization, the new organization must continue to meet the SBIR / STTR program eligibility requirements. Recipients should contact the NIH awarding office to discuss options when considering a move to a new organization.

18.5.2.3 Minimum Level of Effort

Generally, under SBIR Phase I awards, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the SBC. Payments, in the aggregate, to consultants, consortium participants and contractors for portions of the scientific/technical effort generally may not exceed 33 percent of the total requested amount.

Generally under SBIR Phase II awards a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the SBC. In addition, payments, in the aggregate, to consultants, consortium participants, and contractors for portions of the scientific/technical effort generally may not exceed 50 percent of the total requested amount.

Deviations from these requirements may be considered on a case-by-case basis for SBIR only and must be approved in writing by the awarding IC

For STTR awards (both Phase I and Phase II), at least 40 percent of the work must be performed by the SBC and at least 30 percent of the work must be performed by the single, non-profit research institution. These percentages are Congressionally mandated and waivers are not permitted. The basis for determining the percentage of work to be performed by each of the cooperating parties is the total cost (direct and F&A costs, and fee) attributable to each party, unless otherwise described and justified in the "Consortium/Contractual Arrangements" portion of the of the grant application.

18.5.2.4 Multiple Program Director/Principal Investigator Applications and Awards

The Multiple Program Director/Principal Investigator (multiple PD/PI) option is available for NIH SBIR / STTR prime applicants for team science efforts. All of the policy and requirements described in Multi PD/PI apply to SBIR/STTR projects, with the exception of sections that are not relevant to the SBIR/STTR program (e.g., new investigators, multi-project applications). In addition, the following criteria apply to multiple PD/PI SBC applicants and awards:

- The small business concern (SBC) is *always* the applicant/awardee organization. Organizations other than the SBC with PD/PIs participating in the multiple PD/PI project, including the STTR non-profit research institution partner, are subcontractors to the SBC.
- For Phase I SBIR projects, the Contact PD / PI must meet the primary employment requirement; other PD / PIs are not required to meet the requirement. Primary employment means that more than one half of the PD/PI's time is spent in the employ of the SBC at the time of award and during the conduct of the proposed project. However, deviations from this requirement are allowable under exceptional circumstances (such as unexpected loss of a PD/PI or to mitigate negative effects on employment benefits) and must be approved in writing by the awarding IC. To receive a deviation a small business must show:
    - Significant PI employment at the company;
    - Significant commitment of the PI to the project;
    - Commitment to transition the PI to 51% or more employment in the Phase II.
- For Phase II SBIR projects, the Contact PD/PI must meet the primary employment requirement; other PD/PIs are not required to meet the requirement. Deviations from this requirement in Phase II are extremely rare (e.g., the unexpected passing of a PD/PI) and must be approved in writing by the awarding IC.

- For Phase I and Phase II STTR projects, the PD/PI is not required to be employed by the SBC. However, the Contact PD/PI, the first PD/PI listed, must have a formal appointment with, or commitment to, the SBC, which must be in the form of an official relationship between the parties, but need not include a salary or other form of remuneration. Each PD/PI on a multiple PD/PI award must commit a minimum of 1.2 calendar months (10% effort) to the project.
- An STTR applicant organization must officially affiliate a PD/PI with the SBC in the eRA Commons if the PD/PI is not an employee of the SBC.
- A Phase IIB Competing Renewal submitted as a multiple PD/PI application requesting support for a project previously supported through a single PD/PI award should state the changes in the Project's direct and management that led to the proposed multiple PD/PI model.

18.5.3 Public Policy Requirements and Objectives

Commercial organizations receiving SBIR/STTR awards generally are subject to the same public policy requirements as non-profit organizations. However, the requirements concerning reporting of financial conflicts of interest (see Public Policy Requirements, Objectives, and Other Appropriation Mandates—Financial Conflict of Interest in IIA) do not apply to applications or awards under Phase I of the SBIR/STTR programs. The requirements do, however, apply to Phase II applications and awards.

Consistent with SBA program policy directives and NIH's omnibus FOAs for SBIR and STTR, when purchasing equipment or a product under the SBIR/STTR award, the small business concern should purchase only American-made items whenever possible.

18.5.4 Allowable Costs and Fee

18.5.4.1 Program Levels (Total Costs)

The SBA SBIR and STTR Policy Directive provides program levels for SBIR and STTR programs based on statutory guidelines. Agencies have the discretion to issue awards up to the SBA guideline when the proposed budget and requested period of support are fully justified and scientifically appropriate in relation to the proposed research. The Small Business Administration may adjust award guidelines annually. The current SBA budget levels can be found on NIH's SBIR web page.

As written in the statute and under appropriate circumstances, NIH has received waivers from SBA to issue an award exceeding the SBA budget levels for Phase I or for Phase II if this cap will interfere with NIH's ability to meet its mission. See NIH's SBIR web page for a current list of waiver topics.

Applicants must request an appropriate level in the competing application; applications will not be adjusted after submission.

18.5.4.2 Profit or Fee

A reasonable profit or fee may be paid to a SBC receiving an award under Phase I or Phase II of the SBIR and STTR programs. However, this profit or fee must be included in the budget request at the time of application. The profit or fee is not considered a "cost" for purposes of determining allowable use, program income accountability, or audit thresholds. The profit or fee may be used by the SBC for any purpose, including additional effort under the SBIR/STTR award. It is intended to provide a reasonable profit consistent with normal profit margins for commercial organizations for R&D work; however, the amount of the profit or fee normally will not exceed seven (7) percent of total costs (direct and F&A) for each phase of the project. The profit or fee should be drawn from PMS in increments proportional to the drawdown of funds for direct and F&A costs. The profit or fee applies solely to the SBC receiving the SBIR/STTR award and not to any other participant; however, in accordance with normal commercial

practice, the SBC may pay a profit or fee to a contractor providing routine goods or services to the SBC under the grant.

18.5.4.3 Facilities and Administrative Costs (Indirect Costs)

18.5.4.3.1 Phase I

If the applicant SBC has a currently effective F&A cost rate(s) with a Federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. NIH ICs use the term F&A costs for all types of applicants and recipients; however, commercial organizations will find that DFAS and organizations external to NIH refer to these costs as indirect costs. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose estimated F&A costs at a rate not to exceed 40 percent of the total direct costs. However, SBCs are reminded that only actual F&A costs are to be charged to projects. (If awarded at a rate of 40 percent or less, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with a Federal agency.) NIH will not negotiate indirect cost rates for Phase I awards.

18.5.4.3.2 Phase II

If the applicant SBC has a currently effective negotiated indirect cost rate(s) with a Federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. (However, the rates (s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose an estimated F&A rate in the application. If the requested F&A cost rate is 40 percent of total direct costs or less, no further justification is required at the time of award, and F&A costs will be awarded at the requested rate. However, SBCs are reminded that only actual F&A costs may be charged to projects. If awarded at a rate of 40 percent or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with DFAS. DFAS—the office authorized to negotiate indirect cost rates with SBC's receiving NIH SBIR/STTR awards—will negotiate indirect cost rates for SBCs receiving Phase II awards that requested a rate greater than 40 percent of total direct costs.

Upon request, the applicant SBC should provide DFAS with an indirect cost proposal and supporting financial data for its most recently completed fiscal year. If financial data is not available for the most recently completed fiscal year, the applicant should submit a proposal showing estimated rates with supporting documentation. Further information about DFAS is available at its web site or by telephone (see Part III).

18.5.5 Administrative Requirements

Commercial organizations that receive SBIR/STTR awards generally are subject to the same administrative requirements as non-profit organizations. (See 2 CFR Part 200 and 45 CFR Part 75 for further.)

18.5.5.1 Market Research

NIH will not support market research, including studies of the literature that lead to a new or expanded statement of work, under the grant except for the Technical and Business Assistance (TABA) funds or with the Commercialization Readiness Pilot. No SBIR/STTR funds (direct or indirect costs) can be used to support commercialization. For purposes of the SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the

sale and distribution of the subject of the proposed research. It includes various types of research, such as the size of potential markets and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that include a survey of the public as part of the objectives of the project to determine the impact of the subject of the research on the behavior of individuals.

18.5.5.2 Intellectual Property

Rights to data, including software developed under the terms of any funding agreement resulting from an NIH award, shall remain with the recipient except that any such copyrighted material shall be subject to a royalty-free, nonexclusive and irrevocable license to the Federal government to reproduce, publish or otherwise use the material, and to authorize others to do so for Federal purposes. In addition, under the SBIR/STTR programs, in contrast to awards to commercial organizations under other support mechanisms, such data shall not be released outside the Federal government without the recipient's permission for a period of 20 years from completion of the project.

Rights in Data Developed Under SBIR Funding Agreement. Section 9 of the Small Business Act, as amended (15 U.S.C. 638) provides for "retention by a small business concern of the rights to data generated by the concern in the performance of an [SBIR/STTR] award for a period of not less than 4 years."

1. The Act provides for retention by a small business concern (SBC) award recipient of the rights to data generated by the concern in the performance of an SBIR/STTR award. These data rights provide an incentive for SBCs to participate in Federally-funded research projects and contribute to the ability of small business recipients to commercialize the technology developed under the program. The central purpose of SBIR/STTR data rights is to provide the Federal Government with the degree of access to a recipient's SBIR/STTR data needed to evaluate the work and effectively utilize the results and at the same time ensure that the Federal Government or other concerns cannot use SBIR/STTR data in ways (e.g., for commercial purposes or to produce future technical procurement specifications) that would inappropriately diminish the rights or associated economic opportunities of the small business that developed the data. The SBIR/STTR data rights provisions and definitions are designed to ensure that, for properly marked SBIR/STTR data, during the SBIR/STTR protection period, the Federal Government provides effective protection of the data that is comparable to and at least as strong as the protection the Federal Government gives to delivered proprietary data that is developed exclusively at private expense.

2. SBIR/STTR participating agencies must ensure that recipients of an SBIR/STTR funding agreement retain appropriate proprietary rights for all SBIR/STTR data generated in the performance of the award. In general, this results in the Government receiving SBIR/STTR data rights in all SBIR/STTR data during the SBIR/STTR protection period, except for certain types of data that are not subject to such data rights restrictions due to the nature of the data (e.g., Form, Fit, and Function Data or OMIT Data). SBIR/STTR data rights apply to all SBIR/STTR awards, including subcontracts or subgrants to such awards, that fall within the statutory definition of Phase I, II, or III of the SBIR/STTR programs, as described in § 4 of the SBA Policy Directive effective May 2, 2019. The scope and extent of the SBIR/STTR data rights applicable to Federally-funded Phase III awards are identical to the SBIR/STTR data rights applicable to Phases I and II SBIR/STTR awards. SBIR/STTR data rights provide license rights to the Federal Government. SBIR/STTR data rights restrict the Federal Government's use and release of properly marked SBIR/STTR data only during the SBIR/STTR protection period; after the protection period, the Federal Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for government purposes, and is relieved of disclosure prohibitions related to such government purposes, and assumes no liability for unauthorized use of these data by third parties. The Federal Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.
3. 3. SBIR/STTR Data Rights – Main Elements:
    a. An SBC retains title and ownership of all SBIR/STTR data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR data that are not granted to the Government in accordance with the SBA Policy Directive. These rights of the SBC do not expire.
    b. The Government receives SBIR/STTR data rights during the SBIR/STTR protection period on all appropriately marked SBIR/STTR data. These rights enable the Federal Government to use SBIR/STTR data in limited ways within the Government, such as for project evaluation purposes, but are intended to prohibit uses and disclosures of the SBIR/STTR data that may undermine the SBC's future commercialization of the associated technology. The Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.
    c. After the SBIR/STTR protection period has expired, the Federal Government may use, and authorize others to use on its behalf, for government purposes, SBIR/STTR data that was subject to SBIR/STTR data rights during the SBIR/STTR protection period.
4. The SBIR/STTR protection period begins with award of an SBIR/STTR funding agreement and ends twenty years, or longer at the discretion of the participating agency, from the date of award of an SBIR/STTR funding agreement (either Phase I, Phase II, or Federally-funded SBIR/STTR Phase III) unless subsequent to the award, the agency and the SBC negotiate for some other protection period for the SBIR/STTR data.

5. To receive the protections accorded to SBIR/STTR data pursuant to SBIR/STTR data rights, any SBIR/STTR data that is delivered must be marked with the appropriate SBIR/STTR data rights legend or notice, in accordance with agency procedures. The Government assumes no liability for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR data without markings. If SBIR/STTR data is delivered without the required legend or notice, the SBIR/STTR recipient may, within 6 months of such delivery (or a longer period approved by the agency for good cause shown), request to have an omitted SBIR/STTR data legend or notice, as applicable, placed on qualifying data. If SBIR/STTR data is delivered with an incorrect or nonconforming legend or notice, the agency may correct or permit correction at the recipient's expense of such incorrect or nonconforming notice(s).
6. Negotiated Rights:
    a. An agency must not, in any way, make issuance of an SBIR/STTR award conditional upon the recipient negotiating or consenting to negotiate a specially negotiated license or other agreement regarding SBIR/STTR data. The negotiation of any such specially negotiated license agreements shall be permitted only after award.
    b. Following issuance of an SBIR/STTR award, the recipient may enter into a written agreement with the awarding agency to modify the license rights that would otherwise be granted to the agency during the SBIR/STTR protection period. However, any such agreement must be entered into voluntarily and by mutual agreement of the SBIR/STTR recipient and agency, and not a condition for additional work under the funding agreement or the exercise of options. Such a bilateral data rights agreement must be entered into only after the subject SBIR/STTR award (which award must include an appropriate SBIR/STTR data rights clause) has been signed. Any such specially negotiated license must be in writing under a separate agreement after the SBIR/STTR funding agreement is signed. A decision by the recipient to relinquish, transfer, or modify in any way its rights in SBIR/STTR data must be made without pressure or coercion by the agency or any other party. Any provision in a competitive non-SBIR or SBIR solicitation that would have the effect of diminishing SBIR/STTR data rights shall have no effect on the provision of SBIR/STTR data rights in a resulting Phase I, Phase II, or Phase III award.
7. To ensure that SBIR/STTR recipients receive the applicable data rights, all SBIR and STTR solicitations and resulting funding agreements must fully implement all of the policies, procedures, and requirements set forth in the SBA Policy Directive in appropriate provisions and clauses incorporated into the SBIR/STTR solicitations and awards. Paragraph (5)(d)(3) of Appendix I: Instructions for Preparation of SBIR/STTR Program Solicitations in the SBA Policy Directive provides a sample SBIR/STTR data rights clause containing the key elements that must be reflected in the clause used in Federal Agency solicitations. SBA will report to the Congress any attempt or action by an agency, that it is aware of, to condition an SBIR or STTR award on the negotiation of lesser data rights or to exclude the appropriate data rights clause from the award.

The STTR program requires that the small business recipient and the single, non-profit research institution execute an agreement allocating between the parties intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research. By signing the face page of the grant application, the SBC's AOR certifies that the agreement with the research institution is satisfactory to the SBC and will be effective at the time the grant award is made. Prior to award a copy of the agreement must be furnished to the NIH awarding IC.

SBIR/STTR recipients are covered by 35 U.S.C. 200-212 and 37 CFR Part 401 with respect to inventions and patents (see Grants to For-Profit Organizations—Administrative Requirements—Intellectual Property in this chapter).

18.5.5.3 Data Sharing

Applicants for SBIR Phase II funding of $500,000 or more of direct costs in any single year must comply with NIH DMS policy as modified by the Small Business Act. If the final data would not be amenable to sharing, e.g., proprietary data, the SBC should explain that in the application. In addition, as indicated under Intellectual Property in this chapter, whether or not the award meets the threshold for data sharing, NIH will not release data outside the Federal government without the recipient's permission for a period of 20 years from completion of the project.

18.5.5.4 SBIR Life Cycle Certification

All SBIR Phase I and Phase II recipients must complete a Life Cycle Certification at all times set forth in the Notice of Award (see §8(j) of the SBIR Policy Directive). This includes checking all of the boxes and having an authorized officer of the recipient sign and date the certification each time it is required.

A certification is required at the following times:

- For SBIR Phase I Recipients: At the time of receiving final payment or disbursement from the Payment Management System.
- For SBIR Phase II Recipients: prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System.

SBIR grant recipients are required to submit the Life Cycle Certifications within the I-RPPR and the F-RPPR under Section G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements. SBIR recipients should not select the "Nothing to Report" box in this section. The F-RPPR and I-RPPR must be submitted via eRA Commons no later than 120 calendar days from the period of performance end date. I-RPPR or F-RPPR will not be accepted unless all completed Life Cycle Certification(s) are received. Failure to provide all required completed certification(s) may cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding of further awards, suspension or termination.

This does not impact the SBIR Funding Agreement Certification required by all SBIR applicants for new or renewal grants that is required prior to award of a new award or a competing renewal award.

In addition, SBIR recipients indicate compliance with these certification requirements by drawing or requesting funds from the Payment Management System. If the recipient cannot complete the certification or cannot ensure compliance with the certification process, it should notify the GMO immediately. If resolution cannot be reached, the GMO will void or terminate the grant, as appropriate.

The certification form is available in fillable format. However, the requirements are outlined below.

Overview Certification Information. The Federal government relies on this information ensure compliance with specific program requirements during the life of the award.. The definitions for the terms used in the certification are set forth in the Small Business Act, the SBIR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the Grants Management Officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to the certification does not affect the Government's right to pursue criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing a certification may be prosecuted if they have provided false information.

Recipients will verify and certify the following provisions:

1. The principal investigator spent more than half of their time (based on a 40-hour work week) as an employee of the recipient or has requested and received a written deviation from this requirement from the Grants Management Officer. When a deviation has been approved by NIH, the certification will also document the adjusted percentage of time approved.
2. All, essentially equivalent work, or a portion of the work performed under this project:
    a. Has not been submitted for funding to NIH or another Federal agency.
    b. Has been submitted for funding to NIH or another Federal agency but has not been funded under any other grant, contract, subcontract, or other transaction.
    c. A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Grants Management Officer.
3. Upon completion of the award the recipient will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Grants Management Officer. Options on the certification document will include:
    a. SBIR Phase I: at least two-thirds (66 2/3%) of the research
    b. SBIR Phase II: at least half (50%) of the research
    c. Percent deviation approved in writing by the Grants Management Officer
4. The work is completed and the small business recipient has performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Grants Management Officer. Options on the certification document will include:
    a. SBIR Phase I: at least two-thirds (66 2/3%) of the research
    b. SBIR Phase II: at least half (50%) of the research
    c. Percent deviation approved in writing by the Grants Management Officer
    d. N/A because work is not completed
5. The research / research and development is performed in the United States unless a deviation is approved in writing by the Grants Management Officer.
6. The research / research and development is performed at recipient's facilities with the recipient's employees, except as otherwise indicated in the SBIR application and approved in the Notice of Award.

The recipient will notify the Federal agency immediately if all or a portion of the work authorized and funded under the award is subsequently funded by another Federal agency.

The recipient will further certify that they understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

Finally, the individual certifying on behalf of the recipient will certify they are:

1. An officer of the business concern authorized to represent it and sign the certification on its behalf.
2. Representing on their own behalf, and on behalf of the business concern, that the information provided in the certification, the application, and all other information submitted in connection with the award, is true and correct as of the date of submission.

3. Acknowledging that any intentional or negligent misrepresentation of the information contained in the certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

18.5.5.5 STTR Life Cycle Certification

All STTR Phase I and Phase II recipients must complete a Life Cycle Certification at all times set forth in the Notice of Award (see §8(j) of the SBIR Policy Directive). This includes checking all the boxes on the actual certification document and having an authorized officer of the recipient sign and date the certification each time it is required.

A certification is required at the following times:

- For STTR Phase I Recipients: At the time of receiving final payment or disbursement from the Payment Management System.
- For STTR Phase II Recipients: prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System.

STTR grant recipients are required to submit the Life Cycle Certifications within the I-RPPR and the F-RPPR under Section G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements. STTR recipients should not select the "Nothing to Report" box in this section. The F-RPPR and I-RPPR must be submitted via eRA Commons no later than 120 calendar days from the period of performance end date. I-RPPR or F-RPPR will not be accepted unless all completed Life Cycle Certification(s) are received. Failure to provide all required completed certification(s) may cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding of further awards, suspension or termination.

This does not impact the STTR Funding Agreement Certification required by all STTR applicants for new or renewal grants that is required prior to award of a new award or a competing renewal award.

In addition, STTR recipients indicate compliance with these certification requirements by drawing or requesting funds from the Payment Management System. If the recipient cannot complete the certification or cannot ensure compliance with the certification process, it should notify the GMO immediately. If resolution cannot be reached, the GMO will void or terminate the grant, as appropriate.

The certification is available in fillable format, however, the requirements are outlined below.

Overview Certification Information. Please read carefully the following certification statements. The Federal government relies on this information to determine whether the business is eligible for a Small Business Technology Transfer Research (STTR) Program award. The definitions for the terms used in the certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the STTR Policy Directive and also any statutory and regulatory provisions references in those authorities.

If the Grants Management Officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to the certification does not affect the Government's right to pursue

criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing a certification may be prosecuted if they have provided false information.

Recipients will verify and certify the following provisions:

1. The principal investigator spent more than half of their time as an employee of the recipient or the research institution, or the recipient has requested and received a written deviation from this requirement from the Grants Management Officer. When a deviation has been approved by NIH, the certification will also document the adjusted percentage of time approved.
2. All, essentially equivalent work, or a portion of the work performed under this project:
    a. Has not been submitted for funding by another Federal agency.
    b. Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.
    c. A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Grants Management Officer.
3. Upon completion of the award it will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Grants Management Officer. Options on the certification document will include:
    a. STTR Phase I: at least forty (40%) of the research
    b. STTR Phase II: at least forty (40%) of the research
    c. Percent deviation approved in writing by the Grants Management Officer
4. The small business concern, and not the single, partnering Research Institution, is exercising management direction and control of the performance of the STTR funding agreement.
5. The work is completed and it has performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Grants Management Officer. Options on the certification document will include:
    a. STTR Phase I: at least forty (40%) of the research
    b. STTR Phase II: at least forty (40%) of the research
    c. Percent deviation approved in writing by the Grants Management Officer
    d. N/A because work is not completed
6. The research / research and development is performed in the United States unless a deviation is approved in writing by the Grants Management Officer.
7. The research / research and development is performed at Recipient's facilities with Recipient's employees, except as otherwise indicated in the STTR application and approved in the Notice of Award.

The recipient will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

The recipient will further certify that they understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

Finally, the individual certifying on behalf of the recipient will certify they are:

1. An officer of the business concern authorized to represent it and sign the certification on its behalf.

2. Representing on their own behalf, and on behalf of the business concern, that the information provided in the certification, the application, and all other information submitted in connection with the award, is true and correct as of the date of submission.
3. Acknowledging that any intentional or negligent misrepresentation of the information contained in the certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

Phase I Final RPPR: If a Phase I recipient does not intend to submit a Phase II application within four months of the Phase I project period end date, then Phase I Final RPPR must be submitted to the Grants Management Office of the Awarding Component *within 120* days of the completion date of the Phase I grant period. An Interim-RPPR is required if an application for a Phase II or Phase IIB, respectively, is submitted before a final report for the Phase I award would otherwise be due. In the event that the Type 2/Phase II/Phase IIB application is funded, NIH will treat the Interim –RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's Final-RPPR.

Final RPPR Phase I, Phase II, Phase IIB, CRP: Instructions for the Final RPPR are found on NIH's web site. See in particular, Chapter 7.3, SBIR/STTR RPPRs.

Phase II Data Collection Requirement for Government SBIR Reporting Database: The SBA maintains a Database System on SBIR.gov to track and report on statistics regarding the SBIR and the STTR programs. Each small business concern applying for a Phase II award is required to update the appropriate information in the reporting database on SBIR.gov for any of its prior Phase II awards.

In meeting this requirement, the small business concern may apportion sales or additional investment information relating to more than one Phase II award among those awards, if it notes the apportionment for each award. Each Phase II recipient is required to update the appropriate information in the SBIR.gov database on that award upon completion of the last deliverable (e.g., Final RPPR, Federal Financial Report, Final Invention Statement) under the funding agreement. In addition, the recipient is requested to voluntarily update the appropriate information on that award in the SBIR.gov database annually thereafter for a minimum period of 5 years.

Questions about this requirement may be submitted to SBA directly through the Contact Us/Send Feedback link on SBIR.gov. To register on and use the database system, visit SBIR.gov. Online help is available. SBA will minimize the data reporting requirements of small business concerns, make updating available electronically, and provide standardized procedures.

Project commercialization and sales data can only be viewed by Congress, General Accounting Office (GAO), agencies participating in the SBIR/STTR programs, Office of Management and Budget (OMB), Office of Science and Technology Policy (OSTP), Office of Federal Procurement Policy (OFPP), and other authorized persons (for example, authorized contractors) who are subject to a use and nondisclosure agreement with the Federal Government covering the use of the database. Pursuant to 15 U.S.C. 638(k)(4), information provided to the SBIR.gov database is privileged and confidential and not subject to disclosure pursuant to 5 U.S.C. 552 (Government Organization and Employees); nor must it be considered to be publication for purposes of 35 U.S.C. 102 (a) or (b).

Examples of the data to be entered by applicants into SBIR.gov include revenue from the sale of new products or services resulting from the research conducted under each Phase II award or additional

investment from any source, other than Phase I or Phase II awards, to further the research and development conducted under each Phase II award.

19 RESEARCH PATIENT CARE COSTS

19.1 GENERAL

This chapter provides NIH policy on the determination and reimbursement of research patient care costs under grants. This general policy is intended to be applied in conjunction with the requirements of 2 CFR Part 200, Appendix IX, Hospital Cost Principles. In addition, specific NIH programs may have additional or alternative requirements with which an applicant or recipient must comply.

19.2 DEFINITIONS

Research Patient Care Costs. The costs of routine and ancillary services provided by hospitals to individuals participating in research programs. The costs of these services normally are assigned to specific research projects through the development and application of research patient care rates or amounts (hereafter "rates"). Research patient care costs do not include: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors, (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service , (3) recruitment or retention fees or (4) the data management or statistical analysis of clinical research results.

Hospital. Includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria.

Research Patients. Inpatient and outpatient subjects, volunteers, or donors participating in a research protocol.

Routine Services. Regular room services, minor medical and surgical supplies, and the use of equipment and facilities, for which a separate charge is not customarily made.

Ancillary Services. Those special services for which charges are customarily made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology.

Outpatient Services. Services rendered to subjects/volunteers/donors who are not hospitalized.

Usual Patient Care. Items and services (routine and ancillary) ordinarily furnished in the treatment of patients by providers of patient care under the supervision of the physician or other responsible health professional. Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional health services. These expenses are for care that would have been incurred even if the research study did not exist. The patient and/or third-party insurance generally will provide for reimbursement of charges for "usual patient care" as opposed to not reimbursing those charges generated solely because of participation in a research protocol.

Discrete Centers. Groups of beds that have been set aside for occupancy by research patients and are physically separated from other hospital beds in an environment that normally permits an ascertainable allocation of costs associated with the space they occupy and the service needs they generate.

Scatter Beds. Beds assigned to research patients based on availability. These beds are not physically separate from nonresearch beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital and are not usually distinguishable in terms of services or costs from other general service beds within the hospital.

Cost-Finding Process. The technique of apportioning or allocating the costs of the non-revenue-producing cost centers to each other and to the revenue-producing centers on the basis of the statistical data that measure the amount of service rendered by each center to other centers.

19.3 POLICY

NIH provides funds for research patient care costs under grants and cooperative agreements. Research patients may receive routine services as inpatients or ancillary services as either inpatient or outpatient subjects/volunteers/donors. In order to receive reimbursement for research patient care costs, any hospital that, as a direct recipient of NIH funds, expects to incur more than $100,000 in patient care costs in any single budget period on a single NIH grant must either have in place or take steps to negotiate a research patient care rate agreement with the cognizant CAS office. These rates must be shown in all requests and/or claims for reimbursement of research patient care costs. Hospital recipients that expect to incur $100,000 or less in research patient care costs per budget period on a single NIH grant and patient care for all consortium participants/contractors under grants no matter the dollar figure are subject to the requirements specified in the subsection on Special Procedures for Certain Hospitals below. Failure to negotiate a research patient care rate with CAS when required may result in the disallowance of all research patient care costs charged to a grant.

19.4 ALLOWABLE COSTS

The type of patient and services received are the determining factors for allowing research patient care costs as charges to NIH grants. If the patient is receiving service or care that neither differs from usual patient care nor results in expenses greater than those that would have been incurred if the study had not existed, then the patient is considered to be hospitalized for usual care purposes and the grant will generally not support the costs. When the research extends the period of hospitalization beyond that ordinarily required for usual care, or imposes procedures, tests or services beyond usual care, whether in an inpatient or outpatient setting, the grant may pay the additional costs. The recipient must decide whether, in fact, the hospitalization period, the tests, or the services have been extended beyond or added to what would ordinarily have been expected, and to what extent. Patient care costs for individuals who are receiving accepted treatment according to standard regimens would not ordinarily be acceptable charges to an NIH grant. Similarly, in certain kinds of clinical trials where accepted treatments are compared against new therapies, research patient care costs generally may be charged to a grant only insofar as they are measurements or services above and beyond those that constitute usual patient care and are specified by the study protocol. Acceptable exceptions are listed below.

NIH funds may be used to pay all costs (whether usual care costs or research care costs) for the entire period of hospitalization or research tests or services for individuals who would not have been hospitalized or received such tests or services except for their participation in the research study. Any such exceptions should be documented in the recipient's records. These individuals may include the following:

- Volunteers to whom no health advantages may be expected to accrue as a result of the hospitalization. Examples would be normal controls for metabolic or other studies; people with genetic or certain abnormalities of interest to the investigator; healthy individuals participating in a clinical trial, for example a vaccine trial; and sick people brought to the hospital solely for studies when they otherwise would not require hospitalization.

- Volunteers who are sick and of research importance to the protocol but economically unable or without funds available to them through a responsible third party to pay hospitalization expenses. This includes patients for whom some third-party payer, such as a city, county, or State government, might pay hospitalization expenses in some other hospital but has no responsibility to pay in the hospital in which the approved clinical research is being conducted.
- Volunteers of research importance who are unwilling to spend their own money or use their hospital plan coverage at that particular time. (Fear of more urgent need in the future for both personal funds and health insurance might be one reason for the patient's reluctance to participate in the study.) The investigator has a special responsibility in making the decision to include patients in this group with full charges to the grant, since NIH expects the patient and/or third party to pay the total costs of usual care. However, in exceptional circumstances, the investigator may decide to pay the total expenses for hospitalization, research services, or tests from the grant if this is required to secure timely cooperation of a valuable study patient not otherwise available.

19.4.1 Computing Research Patient Care Costs

Research patient care costs, whether expressed as a rate or an amount, shall be computed in an amount consistent with the principles and procedures used by the Medicare program for determining the portion of Medicare reimbursement based on reasonable costs. Separate cost centers must be established for each discrete bed unit for purposes of allocating or distributing allowable routine costs to the discrete unit.

When provisional rates are used as the basis for award of research patient care costs, the amount awarded shall constitute the maximum amount that the NIH awarding IC is obligated to reimburse the recipient for such costs. Provisional rates must be adjusted if a lower final rate is negotiated.

19.4.2 Facilities and Administrative Costs

F&A costs should not be paid on any cost component representing the cost of research patient care activities. Research patient care rates (routine and ancillary) include F&A costs related to "hospital-type" employees (nurses, medical technicians, and similar personnel) supported as a direct cost under a grant. Therefore, to preclude over-recoveries of costs similar to these F&A costs, salaries and wages of all "hospital-type" employees working on the grant must be excluded from the salary and wage (S&W) base used to claim F&A costs. Related fringe benefits also should be excluded if such costs are part of the S&W base. If a "total-direct-costs" base is used to compute and claim F&A costs, the above-mentioned "hospital-type" salaries also must be excluded from the base as well as any other base costs chargeable to the grant through the application of a research patient care rate.

If the grant or a consortium agreement/contract under a grant provides funding exclusively for research patient care activities, no F&A costs normally will be allowed as a separate cost element since all allocable F&A costs will be accounted for in the routine or ancillary activity costs contained in research patient care rates.

Although foreign organizations are not prohibited from requesting research patient care costs, all F&A expenses must be excluded from the charges to the grant.

19.4.3 Special Procedures for Certain Hospitals

19.4.3.1 Recipients

If a recipient does not meet the threshold for negotiation of a research patient care rate agreement with CAS in a given budget period, as specified under Policy in this chapter, but has a currently negotiated

research patient care rate, that rate will be used in awarding and reimbursing research patient care costs, regardless of the amount that the recipient expects to incur. In all other cases, the recipient will be reimbursed at a rate not to exceed the lesser of actual research patient care costs or the rate included in its Medicare cost report.

19.4.3.2 Consortium Participants/Contractors under Grants

If a hospital incurring research patient care costs is not the recipient, the recipient will be responsible for establishing the rate or amount that will be reimbursed for such costs unless the hospital also is a direct recipient of other HHS awards and in that capacity has established a research patient care rate with CAS.

If a participating hospital expects to incur more than $100,000 in research patient care costs as specified under Policy in this chapter, the recipient must negotiate a rate for that hospital unless the relationship between the recipient and the hospital is considered "less-than-arms-length." In this case, the recipient should contact the GMO to determine whether CAS should negotiate the rate.

If a participating hospital expects to incur $100,000 or less in research patient care costs (as provided under Policy in this chapter), the recipient will use the lesser of actual costs or the rate in the hospital's Medicare cost report as the basis for determining reimbursement. For purposes of this paragraph, the recipient will apply the thresholds to each hospital individually.

19.4.4 Financial Responsibilities

If the costs of patient care are funded by the grant, and whether those costs are classified as usual patient care or research patient care, the amount recovered from third parties must be credited to the grant. However, patient charges must be adjusted for both routine services and ancillaries prior to applying the third-party recoveries. The recipient is obligated to pursue recovery to the fullest extent possible and should be able to document those efforts. An example of such an adjustment follows:

If the standard fee schedule charge for a CT scan is $500, the negotiated research patient care agreement rate is 75 percent, and third-party insurance pays $300, the maximum amount that may be charged to the NIH grant is $75, based on the following calculation.

Standard Fee Schedule X (multiplied by) Negotiated Rate = Cost—(minus) Insurance = Maximum Charge to NIH Grant

$500 x .75 = $375 - $300 = $75

In those instances when the recipient determines that the balance of the patient's bill may be charged to the grant (see Allowable Costs in this chapter), the total bill must be adjusted to cost before applying any third-party recoveries. The remaining balance of allowable costs may then be charged to the grant.

In certain circumstances, funds may be awarded that support tests specifically developed for research purposes that are subsequently billed to third parties. In such cases, funds recovered from third parties must be credited to the grant account.

19.5 PROGRAM REQUIREMENTS

An individual NIH IC/program may adopt special implementing procedures consistent with this section to meet its own specific needs.

19.6 POST-AWARD REQUIREMENTS

Post-award rebudgeting into or out of the patient care costs category is likely to be considered a change in scope and require prior approval of the NIH awarding IC (see Administrative Requirements - Prior Approval Requirements - Change in Scope in IIA).

PART III: POINTS OF CONTACT

Various offices and officials are mentioned throughout the preceding parts of the NIHGPS as sources of information or as responsible for certain activities in the NIH grants process. Contact information for these and other offices and officials is provided in this part. These addresses should not be used for express mail or other types of hand-deliveries. The IC should be contacted to obtain the address to use for express mail.

For each IC that awards grants, a listing is provided for the CGMO as well as an extramural program official that may be contacted for general information. The web address for the IC's home page also is included. Requests related to particular applications submitted or grants awarded should be directed to the individual(s) specified in formal communications from NIH, e.g., in the NoA.

20 INSTITUTES AND CENTERS

Institute/Center	Chief Grants Management Officer	Extramural Program Official
John E. Fogarty International Center (FIC) http://www.fic.nih.gov/	Building 31C, Room B2C29, MSC-2220 Bethesda, MD 20892-2220 301-451-1670	Building 31C, Room B2C29, MSC-2220 Bethesda, MD 20892-2220 301-496-1653
National Cancer Institute (NCI) https://www.cancer.gov/	9609 Medical Center Dr., 2W344 MSC 9710 Bethesda, MD 20892-9710 (for U.S. Postal Service) Rockville, MD 20850 (for express delivery) 240-276-6277	9609 Medical Center Drive, Room 7W444 Bethesda, MD 20892-9750 (for U.S. Postal Service mail) Rockville, MD 20850 (for express delivery) 240-276-6340
National Center for Advancing Translational Sciences (NCATS) https://ncats.nih.gov/	One Democracy Plaza, 6701 Democracy Boulevard, Suite 1036, MSC-4874 Bethesda, MD 20892-4874 301-435-0844	One Democracy Plaza, 6701 Democracy Boulevard, Room 904, MSC-4874 Bethesda, MD 20892-4874 301-827-9239
National Center for Complementary and Integrative Health (NCCIH) https://nccih.nih.gov/	Two Democracy Plaza, 6707 Democracy Boulevard, II Suite 415, MSC-5475 Bethesda, MD 20892-5475 301-594-3788	Two Democracy Plaza, 6707 Democracy Boulevard, II Suite 401, MSC-5475 Bethesda, MD 20892-5475 301-594-2014
National Eye Institute (NEI) http://www.nei.nih.gov	5635 Fishers Lane, Suite 3400, MSC-6419 Bethesda, MD 20892-6419 301-451-2020	5635 Fishers Lane, Suite 3400, MSC-6419 Bethesda, MD 20892-6419 301-451-2020
National Heart, Lung and Blood Institute (NHLBI) http://www.nhlbi.nih.gov	One Rockledge Center 6705 Rockledge Dr. Bethesda, MD 20892-7902 301-827-8024	One Rockledge Center 6705 Rockledge Dr. Bethesda, MD 20892-7902 301-827-5517

Institute/Center	Chief Grants Management Officer	Extramural Program Official
National Human Genome Research Institute (NHGRI) http://www.genome.gov	6700B Rocklede Dr., Room 3182 Bethesda, MD 20892-6908 301-435-7858	6700B Rockledge Dr., Suite 3100 Bethesda, MD 20892-6908 301-496-7531
National Institute on Aging (NIA) http://www.nia.nih.gov	7201 Wisconsin Avenue Gateway Bldg., Room 2N212, MSC-9205 Bethesda, MD 20892-9205 301-496-1472	7201 Wisconsin Avenue Gateway Bldg., Room 2C218F, MSC-9205 Bethesda, MD 20892-9205 301-402-7715
National Institute on Alcohol Abuse and Alcoholism (NIAAA) http://www.niaaa.nih.gov	5635 Fishers Lane, Room 3023, MSC-9304 Bethesda, MD 20892-9304 301-443-4704	5635 Fishers Lane, Room 2085, MSC-9304 Bethesda, MD 20892-9304 301-443-9737
National Institute of Allergy and Infectious Diseases (NIAID) http://www.niaid.nih.gov	5601 Fishers Lane, MSC-9833 Rockville, MD 20892-9833 301-496-7075	5601 Fishers Lane, MSC-9824 Rockville, MD 20892-9824 301-496-7291
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) http://www.niams.nih.gov	6701 Democracy Boulevard One Democracy Plaza, Suite 800, MSC-4872 Bethesda, MD 20892-4872 301-594-5032	6701 Democracy Boulevard One Democracy Plaza, Suite 800, MSC-4872 Bethesda, MD 20892-4872 301-594-5055
National Institute of Biomedical Imaging and Bioengineering (NIBIB) http://www.nibib.nih.gov	6707 Democracy Boulevard, Suite 900, MSC-5469 Bethesda, MD 20892-5469 301-451-4782	6707 Democracy Boulevard, Suite 200, MSC-5477 Bethesda, MD 20892-5477 301-496-9474
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) http://www.nichd.nih.gov	6710B Rockledge Drive, Room 3302 Bethesda, MD 20817-1834 301-496-5001	6710B Rockledge Drive, Room 2216 Bethesda, MD 20817-1834 301-435-6856

Institute/Center	Chief Grants Management Officer	Extramural Program Official
National Institute on Deafness and Other Communication Disorders (NIDCD) http://www.nidcd.nih.gov	6001 Executive Boulevard, Room 8335 MSC-9670 Bethesda, MD 20892-9670 301-402-0909	6001 Executive Boulevard, Room 8345 MSC-9670 Bethesda, MD 20892-9670 301-402-0909
National Institute of Dental and Craniofacial Research (NIDCR) http://www.nidcr.nih.gov	6701 Democracy Boulevard, Room 658, MSC-4878 Bethesda, MD 20892-4878 301-594-4808	6701 Democracy Boulevard, Room 660, MSC-4878 Bethesda, MD 20892-4878 301-594-4805
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) http://www.niddk.nih.gov	6707 Democracy Boulevard 2 Democracy Plaza, Room 731, MSC-5450 Bethesda, MD 20892-5450 301-594-8854	6707 Democracy Boulevard 2 Democracy Plaza, Room 715, MSC-5453 Bethesda, MD 20892-5453 301-594-8834
National Institute on Drug Abuse (NIDA) http://www.nida.nih.gov	6001 Executive Boulevard Neuroscience Center, Suite 4128, MSC-9560 Bethesda, MD 20892-9560 301-443-6710	6001 Executive Boulevard Neuroscience Center, Suite 200, MSC-8401 Bethesda, MD 20892-8401 301-443-2755
National Institute of Environmental Health Sciences (NIEHS) http://www.niehs.nih.gov	530 Davis Drive, Room 3044, K3-11 Morrisville, NC 27560 984-287-3332	530 Davis Drive, Room 3112, K3-13 Morrisville, NC 27560 984-287-3249
National Institute of General Medical Sciences (NIGMS) http://www.nigms.nih.gov	45 Center Drive Natcher Bldg., Room 2AN24J., MSC-6200 Bethesda, MD 20892-6200 301-594-5520	45 Center Drive Natcher Bldg., Room 2AN32B, MSC-6200 Bethesda, MD 20892-6200 301-594-4499
National Institute of Mental Health (NIMH) http://www.nimh.nih.gov	6001 Executive Boulevard Neuroscience Center, Room 6122, MSC 9605 Bethesda, MD 20892-9605 301-443-2811	6001 Executive Boulevard Neuroscience Center, Room 6154, MSC-9609 Bethesda, MD 20892-9609 301-443-3367

Institute/Center	Chief Grants Management Officer	Extramural Program Official
National Institute on Minority Health and Health Disparities (NIMHD) http://www.nimhd.nih.gov/	6707 Democracy Boulevard, Suite 800, MSC 5465 Bethesda, MD 301-594-8412	6707 Democracy Boulevard, Suite 800, MSC 5465 Bethesda, MD 301-402-1366
National Institute of Neurological Disorders and Stroke (NINDS) http://www.ninds.nih.gov	6001 Executive Boulevard Neuroscience Center, Room 3254, MSC-9537 Bethesda, MD 20892-9537 301-496-9231	6001 Executive Boulevard Neuroscience Center, Room 3307, MSC-9531 Bethesda, MD 20892-9531 301-496-9248
National Institute of Nursing Research (NINR) http://www.ninr.nih.gov	6701 Democracy Boulevard One Democracy Plaza, Suite 710, MSC-4870 Bethesda, MD 20892-4870 301-594-6869	6701 Democracy Boulevard One Democracy Plaza, Suite 710, MSC-4870 Bethesda, MD 20892-4870 301-594-0544
National Library of Medicine (NLM) http://www.nlm.nih.gov	6705 Rockledge Drive Rockledge I, Suite 500, MSC-7968 Bethesda, MD 20892-7968 301-496-4222	6705 Rockledge Drive Rockledge I, Suite 500, MSC-7968 Bethesda, MD 20892-7968 301-496-4621

20.1 OTHER NIH OFFICES

NIH Office	Address
Division of Grants Policy Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research	6705 Rockledge Drive, Rockledge I, 8th Floor Bethesda, MD 20892-7974 301-435-0949 301-435-3059 (fax) E-mail: GrantsPolicy@mail.nih.gov
Division of Grants Compliance and Oversight Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research	6705 Rockledge Drive, Rockledge I, 8th Floor Bethesda, MD 20892-7974 301-435-0938 301-435-3059 (fax) E-mail: GrantsCompliance@mail.nih.gov Financial Conflicts of Interest E-mail: FCOICompliance@mail.nih.gov Inventions and Technology Resources (301) 435-1986 E-mail: edison@nih.gov
Division of Grants Systems Integration Office of Policy for Extramural Research Administration Office of Extramural Research	Systems Policy Branch 6705 Rockledge Drive Rockledge I, 8th Floor Bethesda, MD 20892-7974 E-mail: operasystemspolicy@nih.gov Centralized Mailing Address for hard copy submission of documents: NIH Closeout Center Division of Central Grants Processing, OER 6705 Rockledge Drive, 8th Floor Bethesda, MD 20892 (for regular or U.S. Postal Service Express mail) Bethesda, MD 20817 (for other courier/express deliveries only) E-mail: NIHCloseoutCenter@mail.nih.gov

NIH Office	Address
Division of Communications and Outreach Office of Planning and Communication Office of Extramural Research Grants Information (general grants information) https://grants.nih.gov/grants/oer.htm	6705 Rockledge Drive, Suite 5040 301-435-0714 E-mail: GrantsInfo@nih.gov
Division of Central Grants Processing Office of Extramural Research	Centralized Mailing Address for hard copy submission of documents: NIH Closeout Center Division of Central Grants Processing, OER 6705 Rockledge Drive, 8th Floor Bethesda, MD 20892 (for regular or U.S. Postal Service Express mail) Bethesda, MD 20817 (for other courier/express deliveries only) E-mail: NIHCloseoutCenter@mail.nih.gov

NIH Office	Address
Office of Extramural Research E-mail: oer@od.nih.gov https://grants.nih.gov/aboutoer/intro2oer.htm	NRSA Payback Service Center Division of Loan Repayment OER/OD/National Institutes of Health 6700B., Rockledge Drive, Suite 2300, MSC 6904 Bethesda, MD 20892-6904 Phone: (301) 594-1835 or (866) 298-9371 NRSApaybackcenter@mail.nih.gov 2. For issues regarding Human Subjects Protections, Clinical Trials, Inclusion, and Single IRB contact: Division of Human Subjects Research 6705 Rockledge Drive, 8th Floor Bethesda, MD 20892-7982 Human Subjects research protections: OER-HS@nih.gov Clinical trials: Clinicaltrials.disseminatiopolicy@mail.nih.gov Inclusion: inclusion@od.nih.gov Single IRB: SingleIRBpolicy@mail.nih.gov For issues regarding Peer Review contact: Review Policy Officer 6705 Rockledge Drive, 8th Floor Bethesda, MD 20892-7982 ReviewPolicyOfficer@nih.gov. For issues regarding Research Training contact: Division of Biomedical Research Workforce 6705 Rockledge Drive, 8th Floor Bethesda, MD 20892-7982 NIHTrain@mail.nih.gov. For issues regarding SBIR/STTR Programs and conference grants contact: Office of Biomedical Entrepreneurship and Innovation

NIH Office	Address
	6705 Rockledge Drive, 8th Floor Bethesda, MD 20892-7982 301-435-2688 301-480-0146 (fax) Web sites for these topic areas can be found from the main OER Grants site: http://grants.nih.gov/grants/oer.htm
Office of Laboratory Animal Welfare (OLAW) Office of Extramural Research https://olaw.nih.gov/	6700 Rockledge Drive, Suite 2500 MSC-6910 Bethesda, MD 20892 301-496-7163 301-480-3394 (fax) E-mail: OLAW@mail.nih.gov
Center for Scientific Review (CSR) https://public.csr.nih.gov/	Division of Receipt and Referral 6701 Rockledge Drive Rockledge II, MSC-7759 Bethesda, MD 20892-7759 301-435-1115
Center for Scientific Review (CSR) https://public.csr.nih.gov/	For submission of paper competing applications: Center for Scientific Review National Institutes of Health Room 713-K 6701 Rockledge Drive, MSC-7759 Bethesda, MD 20892-7759 (zip code for applications sent by USPS regular or Express mail) Bethesda, MD 20817 (zip code for applications sent using a courier service)
Biosafety, Biosecurity, and Emerging Biotechnology Policy Division Office of Science Policy https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/	6705 Rockledge Drive Suite 750, MSC-7985 Bethesda, MD 20892-7985 301-496-9838 E-mail: SciencePolicy@od.nih.gov

NIH Office	Address
Office of Intramural Research (OIR) https://oir.nih.gov/	1 Center Drive Building 1, Room 160 Bethesda, MD 20892-0151 301-496-1921 301-402-4273 (fax)
Office of Financial Management (OFM) http://ofm.od.nih.gov	Office of Financial Management 2115 East Jefferson Street Bethesda, MD 20892-8500 301-402-9123 301-402-4934 (fax) Electronic submission of Financial Status Reports: https://commons.era.nih.gov/commons
Division of Financial Advisory Services (DFAS) Office of Acquisition Management and Policy (OAMP) https://oamp.od.nih.gov/	6011 Executive Boulevard, Room 549C MSC-7663 Bethesda, MD 20892-7663 301-496-4401 301-402-0177 (fax)
Office of Management Assessment (OMA) https://oma.od.nih.gov/DPI/Pages/Home.aspx	Report allegations of non-criminal misuse of grant funds to: Division of Program Integrity 6011 Executive Boulevard, Suite 601, MSC-7669 Bethesda, MD 20892-7669 301-496-5586 301-480-1204 (fax)

20.2 OTHER HHS GOVERNMENT OFFICES

Office	Address
Advisory Council on Historic Preservation http://www.achp.gov	1100 Pennsylvania Avenue NW Washington, DC 20004 202-606-8503
Office of the Inspector General (OIG) https://www.oig.hhs.gov	Report allegations of criminal offenses to: Office of Inspector General Department of Health and Human Services Attn: HOTLINE PO Box 23489 Washington, DC 20026 1-800-HHS-TIPS (1-800-447-8477) E-mail: HHSTips@oig.hhs.gov http://oig.hhs.gov/fraud/hotline TTY: 1-800-377-4950 Fax: 1-800-223-8164
Office of the Inspector General (OIG) https://www.oig.hhs.gov	Questions concerning audit requirements: HHS National External Audit Review Center Office of Audit Services 601 East 12th Street, Room 0429 Kansas City, Missouri 64106 1-800-732-0679 (voice) https://facweb.census.gov/ Receipt point for single audits commercial organizations: Department of Health & Human Services Audit Resolution Division HHH Building, Room 549D 200 Independence Avenue, SW Washington, DC 20201 AuditResolution@hhs.gov
Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp/	The Tower Building 1101 Wootton Parkway, Suite 200 Rockville, MD 20852 240-453-6900 Toll Free within the U.S. 1-866-447-4777 E-mail: OHRP@hhs.gov

Office	Address
Office of Research Integrity (ORI) https://ori.hhs.gov	The Tower Building 1101 Wootton Parkway, Suite 750 Rockville, MD 20852 240-453-8400 E-mail: askori@hhs.gov
Departmental Appeals Board (DAB) http://www.hhs.gov/dab/	330 Independence Avenue, SW Cohen Building, Room G-644, MS 6127 Washington, DC 20201 202-565-0200
Office for Civil Rights (OCR) http://www.hhs.gov/ocr	Headquarters 200 Independence Avenue, SW Hubert H. Humphrey Building Bldg., Room 509 F Washington, DC 20201 1-800-368-1019
Program Support Center (PSC), Payment Management Services (PMS) http://pms.psc.gov	1-877-614-5533 (PMS Help Desk) 301-443-8362 (fax) E-mail: PMSSupport@psc.gov Payment Management System: https://pms.psc.gov/
Cost Allocation Services (CAS) http://rates.psc.gov/	Mid-Atlantic Field Office (Services Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia and West Virginia) 7700 Wisconsin Ave. Suite 2300 Bethesda, MD 20857 301-492-5081 http://rates.psc.gov/fms/dca/midatlantic.html

Office	Address
Cost Allocation Services (CAS) http://rates.psc.gov/	Northeastern Field Office (Services Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Puerto Rico, the Virgin Islands, Canada and Europe) 26 Federal Plaza Room 41-122 New York, NY 10278 212-264-2069 http://rates.psc.gov/fms/dca/northeastern.html
Cost Allocation Services (CAS) http://rates.psc.gov/	Central States Field Office (Services Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, New Mexico, Ohio, Oklahoma, Texas and Wisconsin) 1301 Young Street Room 732 Dallas, TX 75202 214-767-3261 http://rates.psc.gov/fms/dca/central.html
Cost Allocation Services (CAS) http://rates.psc.gov/	Western Field Office (Services Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, Australia, and Asia) 90 7th Street Suite 4-600 San Francisco, CA 94103-6705 415-437-7820 http://rates.psc.gov/fms/dca/western.html

Office	Address
Federal Audit Clearinghouse (Single Audit Reports)	4700 Silver Hill Road Suitland, MD 20746 Questions: 866-306-8779 govs.fac.ides@census.gov Online submission: Form SF-SAC and Single Audit reporting package must be submitted on line using the Internet Data Entry System (IDES) found at https://facweb.census.gov/