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 (grant number, including the two-letter institute code and six-digit serial number, e.g., CA012345) awarded by the National Institutes of Health. 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 for-profit 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 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 (2 CFR 200.303(a) and (b)). They must evaluate and monitor their compliance with statutes, regulations, and terms and conditions (2 CFR 200.303(c)), and they must take prompt action when instances of noncompliance are identified (2 CFR 200.303(d)).

Recipient organizations' internal controls should be in compliance with guidance in "Standards for Control in the Federal Government." (2 CFR 200.303(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 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 for-profit 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 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 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, 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 , 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. 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 .

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, 2 CFR Part 200.316. 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). 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. 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, 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 2 CFR Part 200.314. 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. 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. 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 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 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) 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 NIH (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 2 CFR Part 200.329, 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 NIH eRA website for a list of pending grant progress reports and due dates. 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 eRA Commons User Guide under Section 10.2 Delegations..

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 advance information from PMS, and adjust recipient-reported disbursements to equal cash advance drawdowns on all non-closed sub-accounts. 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 all recipients this information is pre-populated by PMS 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).

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 the FFR Reconciliation and Financial Closeout Support Center (FFR-C) within the Office of Policy for Extramural Research Administration (OPERA).. 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 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 annual or final FFR. When the revision results in a balance of $20,000 or greater 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. All refunds under $20,000 on closed PMS documents should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts. PMS refund instructions may be found at https://pms.psc.gov/grant-recipients/returning-funds-interest.html. 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).

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 pass-through entity awards any subaward greater than $30,000.

FFATA specifies the data that should be captured for each pass-through entity 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 pass-through entities 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 (see Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).. 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 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 2 CFR Part 200.337 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 in the NIHGPS (for types of organizations to which 2 CFR Part 200, Subpart F-Audit Requirements do not directly apply). In general, 2 CFR Part 200, Subpart F- Audit Requirements 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 for-profit 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. 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	Federal Audit Clearinghouse (See contact information in Part III)
Colleges & Universities (IHEs)	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Non-Profits	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Hospitals	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
For-Profits	2 CFR 200.501	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.

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 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.

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. The regulatory procedures that pertain to suspension and termination are specified in 2 CFR Parts 200.340 through 200.343.

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.

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, (8.3.3.2.1 Exempt Property and 8.3.3.2.2 Nonexempt Property), 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 award that is terminated,
- any award 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. . 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 (Final RPPR and Final Invention Statement) or PMS (Final FFR), as applicable. 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 For-profit 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. Additional information is available at the NIH Multiple Principal Investigators website.

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 Notice of Funding Opportunity. 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 NOFO 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. For-profit 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 Notices of Funding Opportunity

Construction grant applicants are required to apply in response to a specific NOFO. 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 NOFO, 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 NOFO and NoA. Applicants should consult the NOFO 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 NOFO.

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, 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, 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 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 NOFO. 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 2 CFR Part 200.427. 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 NOFO	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 NOFO and NoA	Specified in the NOFO and NoA	N/A
NIH Design Requirements Manual	Applicable	Specified in the NOFO	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 NOFO and NoA	Specified in the NOFO 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 NOFOs 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 basic biomedical, behavioral, or clinical sciences, in behavioral or social sciences or in health services research.

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 Research Training and Career Development 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 (for-profit 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 NOFO. 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 research involving recombinant or synthetic nucleic molecules. (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

accepted. 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 NOFO.

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 Notice of Funding Opportunity and on NIH's Standard Due Dates website.

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 NOFO. 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 NOFO 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 NOFO 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 NOFO 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 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.

While stipends are not provided as a condition of employment, NIH policy is not intended to discourage or otherwise prevent recipient organizations from hiring NRSA trainees and fellows as employees or providing them with benefits consistent with what the organization provides other employees at similar career stages.

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 currently available 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, for-profit organizations, or foreign organizations, are published in the *NIH Guide for Grants and Contracts*. They also are available on the NIH Institutional Training Grants 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 the NIH Forms Library website 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 organizations. No Activation Notice is required from the new sponsoring organization. The relinquishing sponsoring organization does not need to take any action in xTrain when a Fellowship is being transferred via a Change of Recipient Organization. The appointment will stay active as it currently is in xTrain. The new sponsoring organization of the fellow is responsible for continuing to manage the xTrain forms and performing the termination on behalf of all grant years when the Fellowship award ends.. 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, T35, T35 and T90) 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 is carried out in a manner to encourage individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women 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, social 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. Individuals who have 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 are not eligible for predoctoral training. Students enrolled in an integrated dual degree program leading to any of the degrees described above are eligible for the pre-doctoral training program. An integrated dual degree training program is a postgraduate program that leads to two degrees that are pursued concurrently. The student maintains their predoctoral training status as long as they remain enrolled in the dual degree program, regardless of whether the health professional degree (M.D. D.D.S.) is awarded prior to the research doctoral degree. A student cannot possess both predoctoral and postdoctoral statuses. A student that is not enrolled in a dual degree program and is pursuing both a research degree and health professions degree separately will not maintain their predoctoral status if the student completes one degree prior to completing the other degree (e.g. student completes the M.D. degree prior to completing their Ph.D.).

Students enrolled in health-professional programs that are not part of a formal, dual-degree 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 two years of research, research training, or comparable experiences beginning at the time of appointment.

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 NOFOs.

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 NOFO. 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 NOFOs and NOFOs 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 NIH Standard Due Dates website. (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 Notice of Funding Opportunity 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.

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 prospective 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 or economically 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 tables.

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 describe past recruitment efforts. Renewal applications must also describe the program's experiences in recruiting prospective trainees 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 description 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 NOFO.

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 NOFO 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 NOFO 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 NOFO 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 Recruitment Plan 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 any and 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 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.

While stipends are not provided as a condition of employment, NIH policy is not intended to discourage or otherwise prevent recipient organizations from hiring NRSA trainees and fellows as employees or providing them with benefits consistent with what the organization provides other employees at similar career stages. Institutions should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

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. Generally, 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. The PHS 2271 cannot 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. Trainees are required to sign reappointments and amendments, just as they are required to sign the initial appointments.

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 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, require the trainee signature, 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 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 research involving 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, for-profit, 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 pro-rated. 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 NOFO 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 NOFO.

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 NOFOs. In addition, some ICs may issue IC-specific NOFOs for specialized programs. Specific program requirements for each mentored CDA program are found in the NOFOs. 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 NOFO.

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 NOFO 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 NOFO 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 NOFOs. 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 NOFO 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 NOFO for each CDA.

12.3.1 Eligible Institutions

Applications for CDAs may be submitted on behalf of the candidate by any domestic for-profit or nonprofit 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 NOFO 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 NOFO. 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 NOFO 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, a 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 NOFO. 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 NOFO 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 NOFO. 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), a 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 Notice of Funding Opportunity.

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 NOFO 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 NOFO 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 NOFO 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 NOFO prior to preparing an application to discuss any specific provisions of the award.

The specific NOFO 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 information is available from the NIH Grants & Funding website.

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 NOFO 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 NOFO 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 NOFO.

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 NOFO 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 NOFOs.

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 NOFOs, 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 NOFOs may use special submission dates instead of the standards dates, but the NOFO 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 NOFO. 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 NOFO 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 NOFO 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 NOFO. 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 research involving recombinant or synthetic nucleic acid molecules. 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.

12.13.1 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.

12.13.1.1 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.

12.13.2 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 Notice of Funding Opportunity. When 2271s are required, this information must be submitted using the xTrain feature in the eRA Commons.

12.13.3 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.

12.13.4 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.

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 NIHGPS, 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 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 NOFO. 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 NOFOs.

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 NOFO.

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, 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, provided that meal costs are not duplicated in participants' per diem or subsistence allowances. See Travel below.

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

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, 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, 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.

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 (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) — 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 pass-through entity 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. NIH will not support any agreement that does not meet the minimum requirements outlined in the written agreement section below (15.2.1). NIH reserves the right to request copies of the written agreement and relevant supporting documentation as needed, as part of its oversight responsibilities. Failure to provide requested documentation may lead to remedies for noncompliance and potential enforcement actions (see 8.5, Specific award conditions and remedies for noncompliance).

NIH expects recipients to ask potential subrecipients, at the application stage, to submit language in their letters of support indicating their awareness of these requirements and the subrecipient's willingness to abide by all requirements should an award be issued.

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, signed and agreed to by both parties, with each consortium participant/subrecipient 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. If a subrecipient is unwilling to sign the written agreement outlining the requirements below, then a subaward cannot be issued. 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 pass-through entity 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 pass-through entity or that of the subrecipient will apply to the subrecipient's Investigators.
- If the subrecipient's Investigators must comply with the pass-through entity'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 pass-through entity for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the pass-through entity.
- 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 pass-through entity. Such time period(s) shall be sufficient to enable the pass-through entity 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 pass-through entity'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 pass-through entity. Such time period(s) shall be sufficient to enable the pass-through entity 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).
- For foreign subrecipients, a provision requiring the foreign subrecipient to provide access to copies of all lab notebooks, all data and documentation that supports the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than annually, in alignment with the reporting requirements for the RPPR. Such access may be entirely electronic.

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 pass-through entity does not have an approved domestic or foreign 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 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 for-profit 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, as appropriate.

15.2.6 Audit

The recipient must require consortium participants to comply with the requirements of 2 CFR Part 200, Subpart F or 2 CFR Part 200.501, 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 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 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.

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 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 for-profit 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 Notice of Funding Opportunity (NOFO) allows foreign organizations to apply, international organizations may apply. If the NOFO 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 a NOFO 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. 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 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 NOFOs 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 for-profit organizations (specified 2 CFR Part 200.501 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. Repayment instruction can be found on the HHS Returning Funds website.

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 NOFO. 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, 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) for purposes of determining the accountability requirements of 2 CFR Part 200.313. 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.

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 for-profit 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 for-profit organizations. This chapter addresses separately the policies applicable to for-profit organizations generally, and those that apply to SBIR and STTR awards specifically. It also highlights several policies in IIA that apply equally to for-profit 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

For-profit 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 for-profit 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 for-profit 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 Principles, are used to determine allowable costs under NIH grants to proprietary hospitals.

18.3.2 Facilities and Administrative Costs (Indirect Costs)

F&A costs, including de minimis costs when appropriate, are allowable under awards to for-profit organizations. See "Reimbursement of Facilities and Administrative Costs" on page IIA-68.

18.3.3 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 for-profit 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

For-profit 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 for-profit organizations are indicated below.

18.4.1 Equipment Accountability

For-profit recipients of NIH grants are nonexempt and subject to the requirements in 2 CFR Part 200.313, 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, for-profit 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, for-profit 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 for-profit organizations, whether small businesses or large businesses. However, invention reporting requirements for for-profit organizations differ somewhat from those for non-profit organizations. When the recipient is a for-profit 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, for-profit 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 for-profit 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 for-profit organizations are specified in 2 CFR Part 200.501. For-profit organizations are subject to requirements for non-Federal audits. A for-profit 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.

For-profit 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 for-profit organizations).

NIH requires for-profit 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 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 Notices of Funding Opportunity. 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 Notices of Funding Opportunity.

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 NOFO 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 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

For-profit 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 NOFOs 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 an 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 for-profit 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, for-profit 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

For-profit organizations that receive SBIR/STTR awards generally are subject to the same administrative requirements as non-profit organizations. (See 2 CFR Part 200.)

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 for-profit 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 Notice of Funding Opportunity 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 Notice of Funding Opportunity 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.

18.5.5.6 Final RPPR

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.

18.5.5.7 Phase II Data Collection Requirement for Government SBIR Reporting Database

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 Rockledge 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 3039, 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 20892-5465 301-594-8412	6707 Democracy Boulevard, Suite 800, MSC 5465 Bethesda, MD 20892-5465 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
Closeout Center Division of Grant Systems Integration Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research	NIH Closeout Center Office of Policy for Extramural Research Administration (OPERA), 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
Division of Foreign Interference, Research Misconduct and Harassment Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research	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) 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 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

NIH Office	Address
Division of Grant Systems Integration Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research	Systems Policy Branch 6705 Rockledge Drive Rockledge I, 8th Floor Bethesda, MD 20892-7974 E-mail: operasystemspolicy@nih.gov
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/	6700B 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 301-435-0715 Email: csrdrr@mail.nih.gov
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)
Office of Science Policy https://osp.od.nih.gov/	6705 Rockledge Drive Suite 630, 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 6701 Rockledge Drive, 3rd Floor Bethesda, MD 20892-7784 301-496-6088 301-402-4934 (fax)
Division of Financial Advisory Services (DFAS) Office of Acquisition Management and Policy (OAMP) https://oamp.od.nih.gov/	6701 Rockledge Dr. 4th floor, Bethesda, MD 20817 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 Office of Management Assessment National Institutes of Health 6705 Rockledge Drive, RK1-RM 605-Q 301-496-5586 301-480-1204 (fax)

20.2 OTHER HHS GOVERNMENT OFFICES

Office	Address
Advisory Council on Historic Preservation http://www.achp.gov	401 F Street NW Suite 308 Washington, DC 20001 202-517-0200 Email: achp@achp.gov
Office of the Inspector General (OIG) https://www.oig.hhs.gov	Report allegations of criminal offenses to: U.S. Department of Health and Human Services Office of Inspector General ATTN: OIG HOTLINE OPERATIONS P.O. 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
HHS National External Audit Review Center https://facweb.census.gov/	Questions concerning audit requirements: Office of Audit Services 1100 Walnut Street, Suite 850 Kansas City, Missouri 64106 1-800-732-0679 (voice) Email: https://facweb.census.gov/ Receipt point for single audits for-profit organizations: Department of Health & Human Services Audit Resolution Division HHH Building, Room 549D 200 Independence Avenue, SW Washington, DC 20201 AuditResolution@hhs.gov

Office	Address
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 of Research Integrity (ORI) https://ori.hhs.gov	The Tower Building 1101 Wootton Parkway, Suite 240 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/

Office	Address
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. Bethesda, MD 20857 Email: cas-bethesda@psc.hhs.gov PHONE: (301)443-5625 Director Phone Number Director # Darryl Mayes (301) 492-4852
Cost Allocation Services (CAS)	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 New York New York10278 cas-ny@psc.hhs.gov PHONE: (212) 264-2069 Director Phone Number Darryl Mayes (301) 492-4852

Office	Address
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 St Dallas Texas75202 cas-dallas@psc.hhs.gov PHONE: (214) 767-3261 FAX: (214) 767-3264 Director Phone Number Arif Karim (214)767-3600
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 San Francisco, California 94103 United States cas-sf@psc.hhs.gov PHONE: (415) 437-7820 Director's Phone Number Arif Karim (214)767-3600

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/

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

May 27, 2025

Dr. Shannon Schechter
University Of California At San Francisco
Shannon.Schechter@ucsf.edu

Dear Dr. Shannon Schechter:

On March 21 2025, the National Institutes of Health (NIH) terminated your project entitled "Examining differential effects of state equality-promoting policies on harmful alcohol use among sexual and gender minority adults in the U.S.: an econometrics approach for causal inference" under grant F31AA030722-02 to the University of California at San Francisco.

NIH terminated the project on the grounds that the research activities do not align with the agency's priorities. You have submitted an appeal requesting NIH to reconsider its award action. As such, NIH has conducted a careful assessment of your request for reconsideration of the determination, and have identified the following:

The program that supported this award was terminated because it is no longer aligned with NIH/HHS priorities. Consequently, awards made through this program can no longer be supported and the request for reinstatement cannot be granted. NIH encourages the awardee to submit a new application that aligns with NIH's priorities under one of NIH's active NOFOs.

We appreciate your patience while we reassessed this matter.

Sincerely,

Matthew J. Memoli, M.D., M.S.
Principal Deputy Director, NIH

National Institutes of Health
Office of Strategic Coordination–The Common Fund

April 7, 2025

Jenny Scanlin
Housing Authority of the City of Los Angeles
jenny.scanlin@hacla.org

Dear Jenny Scanlin:

Effective with the date of this letter, funding for Project Number OT2 OD035940-01 is hereby terminated pursuant to the terms of the Other Transactions (OT) award agreement. This letter constitutes a notice of termination.

NIH has determined that a termination is in the Government's best interest, because this award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. It is the policy of NIH not to prioritize such research programs. Therefore, there is no modification of the project that would align with agency priorities.

Although NIH generally will suspend (rather than immediately terminate) awards and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, no corrective action is possible here. To comply with the OT award conditions the Division of Other Transactions Management will set up an official meeting to discuss the orderly closeout of the OT project.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed in the OT agreement. However, due to the immediate termination of this project, NIH may require a shortened timeframe to submit closeout reports. Details will be provided in the revised NOA issued by the Other Transactions Agreements Officer.

Administrative Appeal

Should you object to the termination, you may provide information and documentation challenging this action. You must submit a request for such review to Acting Principal Deputy Director Dr. Memoli (matthew.memoli@nih.gov) no later than 30 days after the date of this letter. You may submit an extension request to Dr. Memoli and provide good cause as to why an extension of time should be granted.

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 your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.

Sincerely,

ESTHER L. YOUNG -S
Digitally signed by ESTHER L. YOUNG -S
Date: 2025.04.07 18:48:58 -04'00'

Esther L. Young
Other Transactions Agreements Officer

cc:
OPERA Director
Deputy Director for Extramural Research

From: Bulls, Michelle (NIH/OD) [E]
To: Bulls, Michelle (NIH/OD) [E]
Subject: FW: Grant Termination Notification
Attachments: image002.png

Michelle G. Bulls
Director, Office of Policy for Extramural Research Administration, OER
National Institutes of Health
6705 Rockledge Drive, Room 803-C
Office: (301) 594-6739
Cell: (240) 550-1977
Email: michelle.bulls@nih.gov

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Monday, March 24, 2025 3:52 PM
To: gavin.rynne@ucsf.edu
Subject: Grant Termination Notification

3/24/2025

Rynne, Gavin
University Of California, San Francisco
gavin.rynne@ucsf.edu

Dear Rynne, Gavin:

Effective with the date of this letter, funding for Project Number 1U19AI171110-01 is hereby terminated pursuant to the Fiscal Year 2022 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2022 Policy Statement applies to your project because NIH approved your grant on 5/16/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2022 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or

in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "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,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

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 your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# U19AI171292
Federal Award Date
04/07/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
104 AIRPORT DR STE 2200
CHAPEL HILL, NC 27599

2. Congressional District of Recipient
04

3. Payment System Identifier (ID)
1566001393A1

4. Employer Identification Number (EIN)
566001393

5. Data Universal Numbering System (DUNS)
608195277

6. Recipient's Unique Entity Identifier
D3LHU66KBLD5

7. Project Director or Principal Investigator
Ralph S Baric, PHD (Contact)
Professor
rbaric@email.unc.edu
919-966-3895

8. Authorized Official
Alexie Mina

Federal Agency Information

9. Awarding Agency Contact Information
Jordan A. Kindbom
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jordan.kindbom@nih.gov
240-669-2983

10. Program Official Contact Information
FAYNA C Diaz San Segundo
Program Official
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
fayna.diazsansegundo@nih.gov
(240) 669-2721

Federal Award Information

11. Award Number
1U19AI171292-01

12. Unique Federal Award Identification Number (FAIN)
U19AI171292

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title
RAPIDLY EMERGING ANTIVIRAL DRUG DEVELOPMENT INITIATIVE- AViDD CENTER (READDI-AC)

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 05/16/2022 **– End Date** 04/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$65,483,194
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$65,483,194
26. Project Period Start Date 05/16/2022 **– End Date** 04/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$65,483,194

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Emily Linde

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH PROJECT COOPERATIVE AGREEMENT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1U19AI171292-01 REVISED

Principal Investigator(s):
Ralph S Baric (contact), PHD
Timothy Willson, PHD

Award e-mailed to: SponsoredPrograms@unc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIV OF NORTH CAROLINA CHAPEL HILL in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number U19AI171292. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Emily Linde
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$8,464,134
Fringe Benefits	$2,446,845
Personnel Costs (Subtotal)	$10,910,979
Consultant Services	$64,500
Materials & Supplies	$2,845,501
Travel	$573,189
Other	$6,125,525
Subawards/Consortium/Contractual Costs	$33,069,143
Publication Costs	$123,000
Tuition Remission	$37,947
Federal Direct Costs	$53,749,784
Federal F&A Costs	$11,733,410
Approved Budget	$65,483,194
Total Amount of Federal Funds Authorized (Federal Share)	$65,483,194
TOTAL FEDERAL AWARD AMOUNT	$65,483,194
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$65,483,194	$65,483,194

Fiscal Information:

Payment System Identifier:	1566001393A1
Document Number:	UAI171292AC6
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022
AI	8051125	$65,483,194

NIH Administrative Data:
PCC: M65C / **OC**: 41026 / **Released**: 04/07/2025
Award Processed: 04/08/2025 12:02:46 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U19AI171292-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1U19AI171292-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

definition of "Research and Development" at 45 CFR Part§ 75.2**.** 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).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) U19AI171292. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data*

reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. 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/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1U19AI171292-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD:

In compliance with the Temporary Restraining Order issued on April 3, 2025, in the United States District Court for the District of Rhode Island, Notices of Award (NOAs) issued on or after March 24, 2025, that instructed termination of certain COVID-19 funding and ceasing of activities under this award for reasons related to the end of the COVID-19 pandemic are officially rescinded. Activities and funding under this award are no longer terminated through April 17, 2025, or the Court rules on the Plaintiffs' motion for a preliminary injunction whichever comes first. Accordingly, award activities may continue consistent with the existing terms and conditions of the award, including applicable regulations.

Therefore, effective with the date of this revised Notice of Award, funding for Project Number 1U19AI171292-01 is hereby fully reinstated; therefore, the termination letter dated March 24, 2025, is rescinded. Funds made available to The University of North Carolina Chapel Hill used to support RAPIDLY EMERGING ANTIVIRAL DRUG DEVELOPMENT INITIATIVE- AViDD CENTER (READDI-AC) are no longer restricted and are available for use in accordance with the terms and conditions of the award.

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The National Institutes of Health (NIH) is conducting a compliance review of awards to the University of North Carolina Chapel Hill with Dr. Ralph Baric as Principal Investigator (PI) or any senior key capacity. To protect NIH's interests during this review, costs for salary, fringe benefits, and associated Facilities & Administration for Dr. Baric are hereby restricted, effective immediately, while NIH conducts its compliance review.

The University of North Carolina Chapel Hill is prohibited from requesting funds to support grants with Dr. Baric as the PI or any senior key capacity from the HHS Payment Management System and no obligations may be made for the benefit of Dr. Baric until such time that the recipient has received a letter from NIH removing the restriction. Failure to comply with this term may result in further actions that may affect future funding per NIH GPS 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support.

Supersedes previous Notice of Award dated **03/25/2025**. All other terms and conditions still apply to this award.

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REVISED AWARD: This award is revised to update the terms and conditions of the award that have been accepted by the recipient on **10/26/2023**.

No funds provided by this award may be used to support research reasonably anticipated to create, transfer, or use an enhanced potential pandemic pathogen per the Department of Health and Human Services (HHS) Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework). Detailed descriptions of all proposed experiments that are determined to or may be reasonably anticipated to meet this scope, must be submitted to NIAID for review and approval prior to any work commencing. Any work that is conducted without prior approval could result in improper payments of such work that is charged to the project. If NIAID determines that HHS review of the proposed studies is required, NIAID may request additional information for inclusion in materials, including but not limited to, supporting evidence for the anticipated phenotypic characteristics of each resulting pathogen, for submission to HHS.

The following studies have been approved by NIAID:

- Studies, including resistance studies, involving the creation, use, or transfer of SARS-CoV-2 viruses that use the Δ3678 SARS-CoV-2 or double ORF-deficient (Δ3a/Δ6, Δ3a/Δ7a, and Δ3a/Δ7b) SARS-CoV-2 viruses as a backbone. Any work with an attenuated virus different from those identified above requires prior approval from NIAID, and may require HHS review.
- Use or transfer of naturally-occurring clinical isolates of circulating viruses.

The following studies, when conducted using strains other than the Δ3678 SARS-CoV-2 or double ORF-deficient (Δ3a/Δ6, Δ3a/Δ7a, and Δ3a/Δ7b) SARS-CoV-2 viruses as backbones, meet the scope of the HHS P3CO Framework, require review by HHS, and no funds from this award may be used to support this research:

- Studies involving the creation, use, or transfer of viruses, that are resistant to approved or authorized drugs, or components thereof, including, but not limited to, Paxlovid™/nirmatrelvir, Lageviro™/molnupiravir, and Veklury™/remdesivir.

Studies with candidate compounds that bind to the same active site and/or have similar chemical structure to approved or authorized drugs, or components thereof, including but not limited to Paxlovid™/nirmatrelvir, Lageviro™/molnupiravir, and Veklury™/remdesivir, that may generate viruses, that are resistant to approved or authorized drugs, or components thereof.

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The currently proposed research funded under this award is not reasonably anticipated to create, transfer, or use an enhanced potential pandemic pathogen. However, should research conducted under this award have unanticipated outcomes potentially falling within this scope, the recipient must stop work immediately on the day the potential unanticipated outcome(s) are observed. On that same day, the institution must notify the NIAID Program Officer, Grants Management Specialist, and appropriate institutional biosafety committee. After review of the unanticipated outcomes, NIAID will communicate to the institution what, if any, actions should be taken with respect to the virus and research-related virus containing materials. NIAID funds cannot be used to resume these experiments unless a revised Notice of Award (NOA) with the approval has been received. Examples of unanticipated outcomes that would meet this scope include:

In vitro Studies

- If applicable - Experiments that result in a virus that has increased infectivity as assessed by assays in cell culture when compared to a parental strain in the presence or absence of an approved or authorized drug. Evidence of increased infectivity can include but is not limited to, a one (1) log decrease in the multiplicity of infection (m.o.i) required to observe clear cytopathic effect, a 50% increase in cell syncytia formation, and/or changes in cell morphology not observed with the parental virus, such as rounding, detaching, and/or clumping of adherent cells.

In vivo Studies
If applicable - Experiments involving vertebrate animals infected with a modified/mutated virus (e.g., viruses generated during the course of deep mutational scanning studies or viruses with resistance to a therapeutic candidate in development) that display unanticipated increases in disease severity (e.g., weight loss, viral titer, disease progression, or mortality) and/or transmissibility when compared to parental strains in the presence or absence of an approved or authorized drug.

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The recipient is strongly encouraged to submit to the NIAID Program Officer all materials to be published or publicly disseminated, and to inform the NIAID Program Officer about the deposition of genomic data in publicly available databases, resulting from this award at least 10 business days prior to submission or public dissemination. The acknowledgement section should state the specific research studies that were supported by this award.

Supersedes previous Notice of Award dated **05/17/2022**. All other terms and conditions still apply to this award.

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REVISED AWARD:

TRANSITION APPLICATION: Continuation of the program is dependent upon funds availability. If funds are available, to be considered for additional funding after the end of the current project period, the recipient must submit a Non-competing Continuation Progress Report. Recipients must follow the instructions for the PHS 2590 found at https://grants.nih.gov/grants/funding/2590/2590.htm to complete the form. All applicable sections must be completed.

The continuation application package is due 03/15/2025 and should be sent via email to the **NIAID GMP Inbox** at niaidgmpinbox@mail.nih.gov and
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jordan.kindbom@nih.gov. When submitting the continuation application package please include "**AViDD Application"** in the subject line of the email and copy the program official identified on the Notice of Award.

Funding for the continuation application will be contingent upon 1) availability of funds 2) assessment of the progress report and determination if the goals were achieved, and 3) review and approval of other documents necessary for continuation. If the extension request is not approved, the awardee will be advised of the decision in writing.

CHANGE IN CARRYOVER:

Due to Future year commitments being removed from this grant and awarded in a separate supplement under a different document number, the Carryover Authority for this award has been removed

Supersedes previous Notice of Award dated 05/17/2022. All other terms and conditions still apply to this award.

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This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIAID prior approval.

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This Notice of Award (NoA) includes funds for UNIVERSITY OF TORONTO / CANADA in the amount of **$3,829,908**.

This Notice of Award (NoA) includes funds for DIAMOND LIGHT SOURCE LTD / UNITED KINGDOM in the amount of **$486,000**.

This Notice of Award (NoA) includes funds for SICHTING VU / NETHERLANDS in the amount of **$522,558**.

This Notice of Award (NoA) includes funds for DUKE UNIVERSITY in the amount of **$1,779,603**.

This Notice of Award (NoA) includes funds for MCGILL UNIVERSITY / CANADA in the amount of **$324,000**.

This Notice of Award (NoA) includes funds for Rutgers, The State University of New Jersey in the amount of **$1,150,224**.

This Notice of Award (NoA) includes funds for UNIVERSITY OF ALBERTA / CANADA in the amount of **$1,539,000**.

This Notice of Award (NoA) includes funds for The Board of Regents of the University of Wisconsin System in the amount of **$5,408,724**.

This Notice of Award (NoA) includes funds for UNIVERSITY COLLEGE LONDON / UNITED KINGDOM in the amount of **$2,656,800**.

This Notice of Award (NoA) includes funds for The Vanderbilt University in the amount of **$1,902,000**.

This Notice of Award (NoA) includes funds for University of Pennsylvania in the amount of **$2,193,750**.

This Notice of Award (NoA) includes funds for Vanderbilt University Medical Center in the amount of **$2,084,190**.

This Notice of Award (NoA) includes funds for University of Maryland Baltimore College in the amount of **$2,128,428**.

This Notice of Award (NoA) includes funds for Oregon Health & Science University in the amount of **$2,772,000**.

This Notice of Award (NoA) includes funds for Janssen Pharmaceutica NV / BELGIUM in the amount of **$1,797,969**.

This Notice of Award (NoA) includes funds for University of Colorado Denver in the amount of **$1,309,847**.

This Notice of Award (NoA) includes funds for The University of Tennessee Health Science Center in the amount of **$1,184,142**.

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This award is issued as a Cooperative Agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the Terms and Conditions of Award set forth in Section VI: Award Administrative Information of **RFA AI-21-050**, which are hereby incorporated by reference as special terms and conditions of award.

The RFA may be accessed at: http://grants.nih.gov/grants/guide/index.html

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Research conducted at the following site(s) must be reported in the Research Performance Progress Report (RPPR), Section G.9 (Foreign component):

- Janssen Global Public Healh Division of Janssen Pharmaceutticals / BELGIUM
- UNIVERSITY OF TORONTO / CANADA
- MCGILL UNIVERSITY / CANADA
- UNIVERSITY OF ALBERTA / CANADA
- Sichting VU / NETHERLANDS
- UNIVERSITY COLLEGE LONDON / UNITED KINGDOM
- DIAMON LIGHT SOURCE LTD / UNITED KINGDOM

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Prior approval is required for the absence, replacement, or substantial reduction in effort for the Program Director/Principal Investigator and the following individuals:

- Kenneth Hugh Pearce
- Cameron Craig
- Timothy Shehan
- Mark Heise

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NIAID has determined that the research proposed in this award may involve one or more of the agents and toxins listed in the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf). As such the recipient must comply with the provisions defined in the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Institutional DURC Policy) (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).

Recipient is required to perform the following:

1. Within 30 calendar days of the date of this award, the Institutional Review Entity (IRE) must review the Program Director/Principal Investigator (PD/PI)'s assessment of whether the research produces, aims to produce, or is reasonably anticipated to produce one or

more of the effects listed in Section 6.2.2 of the Institutional DURC policy referenced above.

   a. If the IRE determines that the research in question does not involve one or more of the categories of experiments detailed in Section 6.2.2 of the Institutional DURC Policy referenced above, the research is not subject to additional review or oversight but must continue to be assessed by the PI as per Section 7.1.A. of the Institutional DURC policy referenced above.
   b. Notify the NIH within 10 calendar days of the institution's determination if the IRE determines that the research in question involves one or more of the categories of experiments detailed in Section 6.2.2 of the Institutional DURC Policy referenced above, regardless of the final DURC determination. This initial notification should include the following information: grant number related to the research; name(s) of PI(s); name(s) of the agent(s) listed in Section 6.2.1 of the Institutional DURC Policy referenced above; and description of why the research is deemed to produce one or more of the experimental effects listed in Section 6.2.2 of the Institutional DURC Policy referenced above. For research that is determined by the IRE to meet the definition of DURC, the notification should also include the name of the investigator (if different from the PI) responsible for the performance of the DURC and a description of the IRE's basis for its DURC determination.

2. If the IRE determines that the research in question is DURC:
   a. Provide the NIH, for review and approval, with a draft risk mitigation plan(s) (developed as per Section 7.2.B.v of the Institutional DURC Policy referenced above) within 90 calendar days of the IRE's determination that the research is DURC.
   b. Research that has been determined to be DURC must be conducted in accordance with the approved risk mitigation plan(s).
   c. The IRE must review the risk mitigation plan(s) at least annually and notify the NIH of any modifications within 30 calendar days of IRE review. Any changes to the risk mitigation plan must be reviewed and approved by the NIH.
3. Notify the NIH within 30 calendar days of any change in the DURC status, including whether the research is determined by the IRE to no longer meet the definition of DURC.
4. Report to NIH within 30 calendar days instances of noncompliance, as well as measures undertaken by the institution to prevent recurrences of similar noncompliance, with the Institutional DURC Policy and approved risk mitigation plan(s).

Submit to the NIAID Program Officer all materials to be published resulting from this grant at least 10 business days prior to submission.

For assistance in implementing and complying with the Institutional DURC policy, please see the DURC Companion Guide, entitled "Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern" (http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf). This document was developed to assist institutions, investigators, and IREs in the development of policies and practices for the effective oversight of DURC and in the execution of some of the required steps for institutional review and oversight including the development of risk mitigation plans.

The level of support of this grant award may be adjusted upon completion of all DURC assessments of the proposed research and the NIH-approved Risk Mitigation Plan. Failure to comply with the term and condition of award may result in an enforcement action as outlined in the NIH Grants Policy Statement 8.5, "Special Award Conditions and Enforcement Actions."

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Recipients conducting research involving Select Agents (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.
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Prior to conducting a restricted experiment with a Select Agent or Toxin, recipients must notify the NIAID and must request and receive approval from CDC or APHIS.

Be advised that the recipient is responsible for having its subrecipients comply with the requirements pertaining to the use of Select Agents and/or Highly Pathogenic Agents.

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Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

> If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.
>
> If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.
>
> If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:
>
> > Any NIAID pre-approved changes in the use of the Select Agents and/or Highly Pathogenic Agents including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or official.
> >
> > If work with a new or additional Select Agents and/or Highly Pathogenic Agents is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by the IBC or equivalent body or official. It is important to note if the work is being done in a new location;
- Any biosafety incidents that occurred and were reported to NIH/NIAID.

SPREADSHEET SUMMARY
AWARD NUMBER: 1U19AI171292-01 REVISED

INSTITUTION: UNIV OF NORTH CAROLINA CHAPEL HILL

Budget	Year 1
Salaries and Wages	$8,464,134
Fringe Benefits	$2,446,845
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Personnel Costs (Subtotal)	$10,910,979
Consultant Services	$64,500
Materials & Supplies	$2,845,501
Travel	$573,189
Other	$6,125,525
Subawards/Consortium/Contractual Costs	$33,069,143
Publication Costs	$123,000
Tuition Remission	$37,947
TOTAL FEDERAL DC	$53,749,784
TOTAL FEDERAL F&A	$11,733,410
TOTAL COST	$65,483,194

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$7,370,036
F&A Costs 1	$4,090,370
F&A Cost Rate 2	55.5%
F&A Cost Base 2	$6,885,621
F&A Costs 2	$3,821,520
F&A Cost Rate 3	55.5%
F&A Cost Base 3	$6,885,621
F&A Costs 3	$3,821,520

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

May 28, 2025

Dr. Alene Denson
University of Massachusetts System--University of Massachusetts at Amherst
opam@umass.edu

Dear Dr. Alene Denson:

On April 2, 2025, the National Institutes of Health (NIH) terminated your project entitled "Peroxisomal quality control mechanisms" under grant R00GM146026-03 to the University of Massachusetts System--University of Massachusetts at Amherst.

NIH terminated the project on the grounds that the research activities do not align with the agency's priorities. You have submitted an appeal requesting NIH to reconsider its award action. As such, NIH has conducted a careful assessment of your request for reconsideration of the determination, and have identified the following:

The program that supported this award was terminated because it is no longer aligned with NIH/HHS priorities. Consequently, awards made through this program can no longer be supported and the request for reinstatement cannot be granted. NIH encourages the awardee to submit a new application that aligns with NIH's priorities under one of NIH's active NOFOs.

We appreciate your patience while we reassessed this matter.

Sincerely,

Matthew J. Memoli, M.D., M.S.
Principal Deputy Director, NIH