Important Note:

This file is **Part 2 of 2** (1.2 MB) containing the NIH Grants Policy Statement (12/03).
The file for **Part 1 of 2** (1.2 MB) may be found at the following URL:

http://grants1.nih.gov/grants/policy/nihgps_2003/nihgps_2003_1_of_2.pdf

Links between Parts 1 and 2 will not function, since these are separate files.
However, Bookmarks shown to the left have will function properly in each file.
The split files are provided for those that experience problems viewing or printing
the larger single PDF file (2.6 MB), which is available for downloading at URL:

http://grants1.nih.gov/grants/policy/nihgps_2003/nihgps_2003.pdf

In addition, the NIHGPS (12/03) is available in HTML format at URL:

http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm

Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, 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 Subpart A of this part because of the type of grant, grantee, or grant-supported activity. Each section of this subpart specifies how the coverage relates to that in Subpart A and must be used in conjunction with Subpart A to determine all of the applicable terms and conditions of a covered type of activity, grantee, or award. Cross-references in this subpart to other sections within this subpart are specifically noted; otherwise the cross-reference is to the cited section in Subpart A.

This subpart contains the following sections:

- Construction grants, including major A&R activities under grants with specific statutory authority for construction or modernization activities (this section also includes requirements for specified A&R activities under nonconstruction grants)
- Individual fellowships and institutional research training grants (also termed "fellowships" and "training grants") under the Kirschstein-NRSA program
- Modular applications and awards
- Conference grants
- Consortium agreements
- Grants to foreign institutions, international organizations, and domestic grants with a foreign component
- Grants to Federal institutions and payments to (or on behalf of) Federal employees under grants
- Grants to for-profit organizations
- Research patient care costs.

CONSTRUCTION GRANTS

General

The following requirements apply to NIH construction grants and major A&R activities under grants with statutory construction or modernization authority (hereafter, "construction grants") and, as specified, to A&R projects under nonconstruction grants. Construction grants are awarded under the C06 activity code or support mechanism.

Except as indicated in this section, these requirements apply to construction grants in lieu of the requirements in Subpart A of this part. Applicants and grantees also should refer to the construction grant program regulations (42 CFR Part 52b), 45 CFR Part 74 or 92, and any applicable IC guidance. Any questions concerning the applicability of particular requirements or policies should be directed to the GMO or other official designated on the NGA.

This section uses the following definitions:

- *Construction.* Construction of new buildings or the modernization of, or completion of shell space in, existing buildings (including the installation of fixed equipment, but excluding the cost of land and off-site improvements).

- *Modernization.* Alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment necessary to make a building suitable for use by a particular program.

Eligibility

In addition to any program-specific eligibility criteria, eligible applicants for construction grants must be public or private non-profit entities and must be located in the United States or in U.S. territories or possessions. For-profit organizations and foreign organizations are not eligible to receive construction grants.

Review and Approval

Construction grant applications are subject to peer review. Review criteria and NIH selection factors are as follows:

- Scientific merit of the research program activities that will be carried out in the proposed facility

- NIH programmatic relevance

- Research and financial need for the project

- Scientific or professional standing or reputation of the applicant and of its existing or proposed officers and research staff

- Relationship to the applicant's overall research programs and impact on relevant research programs and facilities in the geographic area and nationwide
- Availability, by affiliation or other association, of other scientific or health personnel and facilities for carrying out the proposed research program, including, when warranted, the adequacy of a biohazard control and containment program
- Project cost and design.

Public Policy Requirements and Objectives

In addition to the public policy requirements and objectives specified in Subpart A, construction grants are subject to the following public policy requirements. Questions about whether a particular requirement applies to A&R activities under nonconstruction grants should be directed to the GMO. Grantees receiving construction grants 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, Labor Standards, and Other Contract Requirements" in this section.

The 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 probable environmental consequences of any major Federal activity, including grant-supported activities. To comply with NEPA for its grant-supported activities, NIH requires the environmental aspects of construction grants (and certain nonconstruction projects as specified by NIH) to be reviewed and evaluated by NIH technical staff before final action on the application. With respect to earthquakes, structures will be evaluated in accordance with the lateral forces provisions of the Uniform Building Code.

If NEPA applies, the application must be accompanied by the applicant's own separately bound environmental analysis to facilitate review and evaluation for environmental concerns before approval or other action on the application. An environmental analysis means a written review that indicates the expected environmental effects resulting from the proposed action, defines the current and future implications of those effects, and lists any proposed actions or safeguards to avoid or reduce any negative environmental effects. If NIH has not indicated in the RFA that NEPA applies, no environmental analysis is necessary, unless, in an unusual situation, the applicant anticipates a significant environmental consequence or, following receipt of an application, an official of the NIH awarding office indicates the need for an environmental analysis. In those cases, an environmental analysis shall be provided with the application or as requested by NIH.

Public Disclosure

Section 102 of NEPA and EO 11514 (March 5, 1970) provide for public comment and participation in the environmental impact review process. Applicants are required to publicly disclose the project in a newspaper or other publicly available medium and to describe its environmental impact concurrent with notification to the SPOC (see "Intergovernmental Review

under Executive Order 12372" in this section). An example of a suitable 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 2,700 square feet 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 construction noise and increased construction traffic during the construction period. No significant permanent environmental impacts are foreseen. All building permits and zoning approvals have been obtained. 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.

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. The flood insurance purchase requirement applies to both public and private applicants for NIH support. Lists of flood-prone areas that are eligible for flood insurance are published in the *Federal Register* by FEMA.

Historic Properties and Archeological Sites

Under the provisions of the National Historic Preservation Act, as amended, and the Archeological and Historical Preservation Act of 1960, as amended, the Secretary of the Interior has compiled a National Register of Historic Places—sites and buildings of significant importance to U.S. history.[15] The statutes require that, before approval of a construction grant application (or other applications as specified by NIH), NIH take into account the effect on these sites of the proposed construction (or other) project. The applicant must determine whether activities using NIH financial assistance will affect a property listed in the National Register. If a designated historic property will be affected, the applicant must obtain clearance from the appropriate State Historic Preservation Office before submitting the application. Failure to obtain

[15] This list 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, 1100 Pennsylvania Avenue NW, Washington, DC 20004 (telephone: 202-606-8503; website: http://www.achp.gov/). The National Trust for Historic Preservation is located at 1785 Massachusetts Avenue NW, Washington, DC 20036 (telephone: 202-588-6000; website: http://www.nationaltrust.org/).

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.

Intergovernmental Review under Executive Order 12372

EO 12372, Intergovernmental Review of Federal Programs (July 14, 1982), as amended, requires consultation with State and local officials on certain proposed Federal assistance. NIH construction grants are subject to these requirements, as implemented by 45 CFR Part 100, Intergovernmental Review of Department of Health and Human Services Programs and Activities. Applicants (other than federally recognized Indian tribal governments) should contact their SPOC as early as possible to alert the SPOC to the forthcoming application and to obtain necessary instructions on the State process (see http://www.whitehouse.gov/omb/grants/spoc.html for a list of SPOCs). The SPOC is given 60 days to review the application. 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.

Metric System

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, all construction projects supported by NIH grant funds shall be designed using the metric system.

Relocation Assistance and Real Property Acquisition

The Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (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 49 CFR Part 24. Those regulations provide uniform policies and procedures for the acquisition of real property, including acquisition by grantees, 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.

Other Public Policy Requirements

Recipients of NIH construction grants must comply with, or require their contractors to comply with, the requirements set forth in the following:

- 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., for contracts exceeding $100,000

- Uneconomical, hazardous, or unnecessary use of flood plains for construction—EO 11988 (May 24, 1977)

- Provisions for potable water supply—Safe Drinking Water Act (Title XIV of the Public Health Service Act, as amended)

- Conservation of petroleum and natural gas—EO 12185 (December 17, 1979)

Design Requirements for NIH-Assisted Construction[16]

Grantees may not advertise for bids or negotiate a contract for construction or A&R activities exceeding $500,000 in direct costs until working drawings and specifications have been approved by the designated NIH official. One purpose of the NIH review is to apply program-specific design standards to the working drawings and specifications to ensure that program needs are met and the facility will suitably accommodate the activities to be carried out there. In addition, NIH will determine whether the final plans and specifications conform to the minimum standards of construction and equipment specified in 42 CFR Part 52b, in the *NIH Design Policy and Guidelines* issued by NIH's DES, and in the documents cited in this subsection. (The NIH Design Policy and Guidelines are available at http://des.od.nih.gov/eWeb/planning/html/nihpol.htm.) These standards may be modified by DES. The grantee will be subject to the standards in effect at the time of design or construction, as appropriate. NIH will monitor compliance during the project's design phase.

Where State or local codes are proposed as a basis for facility design in lieu of the NIH design requirements, a prior determination must be made by NIH 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 or incorporated in policy guidance, the more stringent requirements will apply.

Elimination of Architectural Barriers to the Physically Handicapped

The Architectural Barriers Act of 1968, as amended, the Federal Property Management Regulations 101-19.6 (41 CFR 101-19.6), and the Uniform Federal Accessibility Standards issued by the General Services Administration (41 CFR 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 grantee proposes to substitute standards that meet or exceed these standards. Where NIH assistance is provided for alteration or renovation (including modernization and expansion) of existing facilities, the altered facility (or part of the facility) must comply, including use of the minimum standards in the specifications. The grantee will be responsible for conducting inspections to ensure compliance with these standards by any contractor performing construction services under the grant. Also see "Public Policy Requirements and Objectives—Civil Rights—Rehabilitation Act of 1973."

[16] References are to the latest editions of cited publications. Grantees and their contractors are responsible for determining what applies at the time of the affected activity.

Seismic Safety for Federally Assisted Construction

The 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. The EO requires that new federally assisted or regulated buildings be designed and constructed using appropriate seismic standards. Where necessary, special structural and other features to protect life and minimize damage to facilities from tornadoes also may be required.

The model codes listed in Exhibit 7 provide a level of seismic safety considered appropriate for implementing EO 12699 and apply to all federally assisted construction in the applicable geographic location. Also acceptable are State, county, or local jurisdictional building ordinances that adopt and enforce these model codes in their entirety or without material revisions that would reduce the level of seismic safety.

Additional Design Requirements

Exhibit 7 lists additional NIH design requirements and their sources.

Exhibit 7. Design Requirements for NIH-Assisted Construction

Requirement	Notes (if appropriate) and source
Model Codes for Seismic Safety	
Uniform Building Code	International Conference of Building Officials 5360 Workman Mill Road Whittier, CA 90601-2298 Telephone: 562-699-0541 or 800-284-4406 Website: http://www.iccsafe.org/e/category.html (Online Product Store)
National Building Code (1999) and National Fire Prevention Code (1999)	Building Officials and Code Administrators Intl., Inc. 4051 West Fossmoor Road Country Club Hills, IL 60478 Telephone: 800-214-4321, ext. 371 Website: http://www.bocai.org/boca-es/
Southern Building Code Congress Standard Building Code (1999),	Southern Building Code Congress International 900 Montclair Road Birmingham, AL 35213-1206 Telephone: 205-591-1853 Website: http://www.sbcci.org (Order and Price List)
Recommended Lateral Force Requirements/Commentary (1999), Structural Engineers Association of California	International Conference of Building Officials 5360 Workman Mill Road Whittier, CA 90601-2298 Telephone: 562-699-0541 or 800-284-4406 Website: http://www.iccsafe.org/e/category.html (Product Store)

Exhibit 7. Design Requirements for NIH-Assisted Construction	
Requirement	**Notes (if appropriate) and source**
Other Design Requirements	
Guidelines for Design and Construction of Hospital and Healthcare Facilities (2001)	AIA, Academy of Architecture for Health Telephone: 202-626-7541 or 800-242-3837 (press 4) Website: http://www.aia.org/publications/
American Society of Heating, Refrigeration, and Air Conditioning Engineers Handbook—HVAC Applications (1999)	ASHRAE Website: http://www.ashrae.org.
Life Safety Code (NFPA Publication 101 and supplements)	NFPA 1 Batterymarch Park Quincy, MA 02269-9101 Telephone: 617-770-3000 or 800-344-3555 Website: http://www.nfpa.org/Codes/index.asp.
Standard on Fire Protection for Laboratories Using Chemicals (NFPA Publication 45)	NFPA 1 Batterymarch Park Quincy, MA 02269-9101 Telephone: 617-770-3000 or 800-344-3555 Website: http://www.nfpa.org/Codes/index.asp
Prudent Practices for Safety in Laboratories (1995)	National Research Council, National Academy Press ISBN 0-309-05229-7 Website: http://books.nap.edu/catalog/4911.html.
National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry (2002)	National Sanitation Foundation 327 Jones Drive Ann Arbor, MI 48105 Telephone: 800-699-9277 Website: http://www.techstreet.com/nsfgate.html
Standard Plumbing Code (2000)	Southern Building Code Congress International 900 Montclair Road Birmingham, AL 35213-1206 Telephone: 205-591-1853 Website: http://www.sbcci.org (Order and Product List)
Industrial Ventilation: A Manual of Recommended Practice (2001)	American Conference of Government Industrial Hygienists 1330 Kemper Meadow Drive Cincinnati, OH 45240-1634 Telephone: 513-742-2020 Website: http://www.acgih.org/Products/
Health Care Facilities Handbook (2002)	NFPA 1 Batterymarch Park Quincy, MA 02269-9101 Telephone: 617-770-3000 or 800-344-3555 Website: http://www.nfpa.org/Codes/index.asp
Standard for Healthcare Facilities (NFPA Publication 99).	NFPA 1 Batterymarch Park Quincy, MA 02269-9101 Telephone: 617-770-3000 or 800-344-3555 Website: http://www.nfpa.org/Codes/index.asp

Exhibit 7. Design Requirements for NIH-Assisted Construction	
Requirement	**Notes (if appropriate) and source**
National Electric Code (NFPA Publication 70)	NFPA 1 Batterymarch Park Quincy, MA 02269-9101 Telephone: 617-770-3000 or 800-344-3555 Website: http://www.nfpa.org/Codes/index.asp
Laboratory Ventilation Codes	American Industrial Hygiene Association 2700 Prosperity Avenue, Suite 250 Fairfax, VA 22031 Telephone: 703-849-8888 Fax: 703-207-3561 Website: http://www.aiha.org/PublicationsAdvertising/html/pubadhome.htm

Funding

Construction grants usually involve a single award, covering more than 1 year, made on the basis of an application for the entire construction project. The project period system of funding normally is not used for construction grants.

Matching

NIH construction grants generally require the grantee to share in the costs of the project. This requirement, if applicable, is stated as a matching percentage; the grantee's match is usually at least 50 percent of the total allowable project costs. Any required non-Federal participation may be in the form of allowable costs incurred by the grantee or a contractor under the grant. Unless required by statute or regulation, NIH generally does not allow grantees to use the value of third-party in-kind contributions as a source of matching. Matching costs and in-kind contributions (if authorized) must meet the allowability and documentation requirements of 45 CFR 74.23 or 92.24, as applicable. Costs claimed as matching also are subject to the requirements of the NIHGPS which 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 will be required to demonstrate that the funds are committed or available before award. This may take the form of an assurance as specified by the NIH awarding office. The amount of NIH (Federal) funds awarded, combined with the non-Federal share, will constitute the total approved budget as shown in the NGA. The prior-approval and other dollar thresholds contained in this section are determined on the basis of the total approved budget unless otherwise specified.

Allowable and Unallowable Costs and Activities

Construction activity is allowable only when program legislation includes specific authority for construction, modernization, or major alteration and renovation of facilities and when NIH specifically authorizes such costs. The following lists indicate types of costs and activities

generally allowable and unallowable under NIH construction grants. The lists are not all-inclusive. Program guidelines and other terms and conditions of the award should be consulted for the specific costs allowable under a particular program or grant.

Allowable costs and activities include the following:

- *Acquisition and installation of fixed equipment.*
- *A&R.* Under programs that have statutory A&R, modernization, or construction grant authority, the costs of adapting any of the following interior building features to the needs of the grant-supported activity are allowable:
  - Physical characteristics of space, such as interior dimensions, surfaces, and finishes
  - Internal environment, such as heating, ventilation, humidity, and acoustics
  - Utility services, such as plumbing, electricity, gas, vacuum, or other laboratory piping
  - Completion of unfinished shell space to make it suitable for purposes other than human occupancy, such as the storage of pharmaceuticals
  - Fixed equipment, such as casework, fume hoods, large autoclaves, or biological safety cabinets.

  A&R costs of this type associated with a building under construction or an otherwise incomplete structure may be allowed if

  - the space is to be adapted to particular program needs,
  - it is cost-effective to perform the work while the building is being constructed or the structure is being completed, and
  - A&R costs are limited to the difference between the cost of completing the interior space for general use and the cost of adapting the space and utilities to meet specific program requirements.

  When the grantee's own construction and maintenance staffs are used in carrying out the A&R (i.e., force account), the associated costs are allowable provided the grantee can document that 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 office.
- *Architectural and engineering services.* Also see "Pre-Award Costs" in this subsection.
- *Bid advertising.*

- *Bid guarantees and performance and payment bonds.* Bid guarantees and performance and payment bonds are allowable as provided in 45 CFR 74.48 or 92.36(h).

- *Contingency fund.* Applicants for construction grants may include a project contingency fund in initial cost estimates to provide for unanticipated charges. These funds will be limited to 5 percent of construction and equipment costs before bids are received and must be reduced to 2 percent after a construction contract has been awarded.

- *Filing fees for recording the NFI.* See "Real Property Management Standards—Notice of Federal Interest" in this section.

- *Inspection fees.*

- *Insurance.* Costs of title insurance, physical destruction insurance, and liability insurance are generally allowable. Physical destruction and liability insurance are usually treated as F&A costs but may be treated as direct costs in accordance with the established policy of the grantee, consistently applied regardless of the source of funds. Title insurance, if required, 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 section).

- *Legal fees.* Legal fees related to obtaining a legal opinion regarding title to a site.

- *Pre-award costs.* Costs incurred before an award for architect's fees and consultant's fees necessary to the planning and design of the project are allowable if the project is subsequently approved and funded.

- *Project management.*

- *Relocation expenses.*

- *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.

Unallowable costs and activities include the following:

- *Bonus payments to contractors.* Bonus payments to contractors, including those to guaranteed maximum price contractors, are unallowable.

- *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.*

- *F&A costs.*
- *Fund-raising expenses.*
- *Land acquisition.*
- *Legal services not related to site acquisition.*
- *Movable equipment.*
- *Off-site improvements.* Off-site improvements such as parking lots are not allowable.

Procurement Requirements for Construction Services under NIH Construction Grants

General

Construction 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. All construction work must be procured by the methods described in 45 CFR 74.40 through 74.48 or in 92.36, as applicable. Normally, this means a prime construction contract is awarded following a competitive sealed bidding process (previously "formal advertising" in Federal contracting) resulting in a lump-sum, fixed-price contract. NIH may authorize other procurement methods and other types of contracts when sealed bidding or a fully competitive negotiated process is impractical. The specific requirements for contracting for construction management services and design-build services are described below.

In general, grantees must do the following:

- Ensure that all qualified contractors are given an opportunity to bid and have their bids fairly considered.
- Guarantee, insofar as possible, that the contract(s) will result in the completion of a facility (ready for occupancy) that conforms to the design and specifications approved by the NIH awarding office (or any appropriate modification thereof with NIH awarding office approval, as required) at a cost within the grantee's ability to pay. (NIH expects that the applicant holds (or will hold) title to the property on which the grant-supported construction is performed.)
- Obtain NIH awarding office approval of plans and specifications both before soliciting bids or proposals and before awarding a prime construction contract. The procurement methods to be employed must be reviewed and approved by the NIH awarding office. The grantee is responsible for ensuring that the project is constructed to completion in accordance with the approved plans or specifications and for obtaining necessary approvals for changes as specified in this section.
- Take adequate steps to ensure that the total cost of construction—i.e., the total cost of all contracts awarded under a project—will be within the amount of funds available for the

project. This can be accomplished by accurate price estimating and/or the use of bid alternates. A precise description of the scope of work, specifications, materials, and construction techniques in the invitation for bids will facilitate accurate cost estimating by both the bidder and the grantee's professional representatives. The description of work becomes especially important when multiple contracts will be let in support of the same project, because each contractor must know exactly what is involved in the portion(s) of the job on which it is bidding.

- In invitations for bids, 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.

Where more than one NIH or HHS program will support a construction project, or where the NIH-supported project is less than the entire facility or construction to be bid, the grantee must obtain bids that provide, to the maximum extent possible, the costs for that portion of the total job that will be financed by NIH funds and any required grantee matching. This may be done by

- showing the cost for each building or site in the project, if it consists of more than one building or construction site and can be divided for bidding and construction purposes, or

- identifying, to the extent possible, or prorating the applicable costs when the project is a single site or contains common space and cannot be divided for bidding and construction purposes.

Where practical, the grantee may request, in the invitation for bids, alternates to the base bid that are keyed to specified and explicitly stated changes in the project scope, materials, or construction techniques. Alternates may be used when it is anticipated that the amount of the low bid will exceed the amount of funds available to the grantee to award a contract, and the grantee must make adjustments to the project to reduce costs in order to award a contract within the funds available. "Add" alternates will make it possible to incorporate necessary features that otherwise would not have been included in the project. Alternates that are selected may be included in determining the low aggregate bid. The grantee must identify, in its bid schedule, whether the low bid will be determined inclusive or exclusive of alternates. If inclusive, then alternates must be awarded in order, up to the amount of funds available. For example, Alternate 1 will be awarded first, Alternate 2 second, Alternate 3 third, etc. No alternate may be awarded out of sequence. If all bids exceed the funds available even after the steps described above have been taken, the grantee may do the following:

- Decline to award a contract and instead issue a revised invitation for bids containing changes in specifications or other factors affecting price that have been approved by the NIH awarding office.

- Negotiate with the low bidder (this is an exception to sealed bidding) or, if that bidder should refuse, in writing, to negotiate, negotiate with the next lowest bidder. Any changes in design and specifications resulting from such negotiations must be approved by the NIH awarding office. If efforts to negotiate are unsuccessful, all bids must be canceled, and the project rebid.

- Obtain approval from the NIH awarding office to authorize a construction management firm already employed by the grantee to perform the construction work. The price for the work involved must not exceed the line-item prices (GMP) stipulated in the construction management contract as approved by the NIH awarding office (see "Construction Management Services" in this section for requirements for a construction management agreement).

- Enter into a design-build contract (see "Design-Build Services" in this section) for a functionally equivalent facility.

Construction Management Services

Construction management services are management services generally procured through negotiation rather than by sealed bidding. These services include technical consultation during the design stage of a project and, during the construction phase, organization and direction of construction activities. In the negotiated procurement process, the RFP must address both the technical qualifications of the offeror (possibly 75 percent of the evaluated score) and the business (cost) aspects of the proposal (possibly 25 percent of the evaluated score). The award must be based on a combination of both the technical and business evaluations. The basis of the award, i.e., whether cost or technical qualifications will weigh more heavily in the award decision, must be stated in the RFP. The services of construction managers may be procured by sealed bidding if State or local governments prohibit the procurement of construction management services through negotiation.

Contracting for construction work on a project covered by a construction management agreement is subject to all of the requirements otherwise applicable to the solicitation and award of contracts, except that bids may be obtained by prequalification and selective solicitation. When prequalification and selective solicitation are used, the construction manager must

- prequalify all firms that respond to the announcement and are determined to meet the prequalification standards;

- establish bidders lists for each of the invitations for bids, including, at least, all prequalified firms, and possibly including other known qualified firms;

- solicit, in writing, bids from all firms on the bidders list;

- consider bids from any contractor who requests permission to bid and who is determined by the grantee to meet the prequalification standards; and

- prepare a bid abstract.

The GMP method may not be used to acquire construction management services under NIH grants unless the grantee obtains NIH prior written approval. If this method is used, the grantee must comply with the following requirements:

- The construction management contract must place total financial responsibility on the construction manager to complete construction of the project at or below the GMP. If the contract exceeds $100,000, the construction manager will be required to comply with bid guarantee and bonding requirements as specified in 45 CFR 74.48(c) or 92.36(h).

- The GMP must be obtained from the construction manager before NIH will authorize the solicitation and 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 to be let shall be separately priced as an individual line item in the GMP contract.

The grantee must transmit all GMP bids to the GMO, with its recommendation for award to the lowest responsive, responsible bidder.

After the award of a GMP contract, the following applies:

- All GMP subcontracts must be bid on the open market, and there must be at least three bidders to allow for an award. If three bids cannot be obtained, the grantee must submit, in writing, to the GMO or other designated official, a detailed explanation of why the GMP contractor is unable to comply, along with supporting documentation for NIH consideration and approval or other action.

- All GMP bids 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 grantee.

- All costs lower than the GMP line item bid as approved by the NIH awarding office shall be refunded or credited to the grantee by the contractor and by the grantee to NIH. All costs in excess of the GMP after all items have been bid are the responsibility of the GMP contractor.

- All subcontract prices must be approved by the NIH awarding office before making individual awards. The awards shall be made to the lowest-priced responsible, responsive bidders.

If a contract with a GMP clause was awarded to a construction management firm before the NIH grant award, the firm's subcontractors must compete in an open competition for the subcontract work under the GMP contract. The GMP contractor must make available to the public all pertinent information that could influence bids and interpretation of the design intent.

Design-Build Services

In design-build contracting, construction firms respond to an RFP by submitting building designs to meet the grantee's performance requirements within a GMP (see GMP requirements under "Construction Management Services" in this section) that covers all required architectural, engineering, and construction services. The design-build firm must be selected in a manner that allows maximum feasible competition. The selection process must include public announcement of the RFP, provided that at least one form of the announcement receives nationwide distribution; consideration of all proposals from firms that are determined to be qualified; and selection based on the firms' qualifications, responsiveness to the criteria in the RFP, and cost.

Because of the nature of design-build contracting, the following departures from sealed bidding are authorized:

- Technical considerations and cost may be treated as competitive factors.
- The grantee may negotiate cost or design with one or more firms.

On all design-build projects, the grantee 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.

Equal Employment Opportunity, Labor Standards, and Other Contract Requirements

Labor standards and equal employment opportunity requirements for federally assisted construction must be specified in the information provided to bidders on construction contracts under NIH grants and must be included in the resulting contract documents (see 45 CFR Part 74, Appendix A, and 45 CFR 92.36(i)). NIH construction grants are not subject to the requirements of the Davis-Bacon Act or the Copeland "Anti-Kickback" Act.

Equal Employment Opportunity

Construction contracts (and subcontracts) awarded under NIH grants are subject to the requirements of EO 11246 (September 24, 1965), as amended, as implemented in 41 CFR Part 60-1 by OFCCP, DoL. The grantee is required to include the "Equal Opportunity Clause" at 41 CFR 60-1.4(b) in any construction contract under the grant. The contractor must be directed to include this clause in any applicable subcontracts.

In addition, grantees and construction contractors 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 (EO 11246)" and the "Standard Federal Equal Employment Opportunity Construction Contract Specifications (EO 11246)."

The OFCCP regulations also require that the grantee notify the applicable OFCCP regional, area, or field office when it expects to award a construction contract that will exceed $10,000.

Further information about these requirements and the full text of these regulations are available at http://www.dol.gov/esa/ofcp_org.htm.

Preservation of Open Competition and Government Neutrality Toward Government Contractors' Labor Relations on Federal and Federally Funded Construction Projects

EO 13202, Preservation of Open Competition and Government Neutrality Towards Government Contractors' Labor Relations on Federal and Federally Funded Construction Projects (February 17, 2001), as amended by EO 13208 (April 6, 2001), requires executive agencies issuing grants, providing Federal assistance, or entering into cooperative agreements for construction projects (including major and minor A&R) to ensure that bid specifications, project agreements, or other controlling documents for construction contracts awarded by recipients of grants, cooperative agreements, or other financial assistance do not do the following:

- Require bidders, offerors, contractors, or subcontractors, or prohibit them, from entering into or adhering to agreements with one or more labor organizations, on the same or other related construction projects.

- Otherwise discriminate against bidders, offerors, contractors, or subcontractors for becoming, refusing to become, or remaining signatories, or otherwise adhering to agreements with one or more labor organizations, on the same or other related construction projects.

Nonsegregated Facilities

Pursuant to 41 CFR 60-1.8, for any contract that will exceed $10,000, the grantee must require each prospective construction contractor to submit a certification that the contractor

- does not, and will not, maintain any facilities it provides for its employees in a segregated manner;

- does not or will not permit its employees to perform their services at any location, under the contractor's control, where segregated facilities are maintained; and

- will obtain a similar certification before awarding any covered subcontract.

Labor Standards

Contract Work Hours and Safety Standards Act

Construction contractors and subcontractors under NIH grants 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. 327-333, 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 grantee 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.

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 grantee, a liquidated damages provision may be included in the construction contract, allowing for assessment of damages when the contractor has not completed construction by the date specified in the contract. Liquidated damages must be real and justified and must be approved by NIH before solicitation. Where damages are assessed, any amounts paid belong to the grantee.

Disposition of Unclaimed Wages

During or after the period of performance of an NIH-assisted construction contract, 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 grantee may eventually have to repay the Federal government. Therefore, NIH suggests that the contractor be required to turn over any unclaimed wages to the grantee.

The grantee 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 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 grantee 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 grantee should attempt to locate the employees. Doing so will reduce the likelihood of future claims against the grantee.

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.

Administrative Requirements

Prior-Approval Requirements

Construction Grants

Grantees must obtain written prior approval from the GMO for grantee-initiated project or budget changes under the following circumstances:

- A revision that would result in a change in scope of the project, including proposed modifications that would materially alter the costs of the project, space utilization, or financial layout, and associated changes in the previously approved solicitation or contract
- A revision that would increase the amount of Federal funds needed to complete the project
- Any other applicable change as specified in "Administrative Requirements—Changes in Project and Budget."

The request for approval must include sufficient information to allow NIH review of the circumstances and need for the proposed change. After receipt of written prior approval from the GMO, the grantee may make or authorize the approved modifications of the construction contract. Other less substantive modifications to construction contracts may be made without the prior approval of the NIH awarding office. However, copies of all change orders to construction contracts must be retained as grant-related records (see "Administrative Requirements—Monitoring—Record Retention and Access").

Alteration and Renovation Projects under Nonconstruction Grants

Two copies of each of the following documents must be submitted with each request for approval of minor A&R costs greater than $300,000, but not more than $500,000 (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/grantees undertaking A&R projects that will require NIH funding of more than $500,000 are subject to the review, approval, and documentation requirements included or referenced in this section for construction grants.

Exhibit 8. Sample Format for A&R Cost Estimate	
Estimate the costs in which the Federal government is requested to participate:	
Cost category	Amount
A&R costs (to Federal government)	
Demolition	$
General alteration and renovation (carpentry, masonry, painting)	$
Plumbing	$
Heating, ventilation, and air conditioning	$
Electrical	$
Architect's and engineer's fees	$
Other costs (specify)	$
Total A&R costs	$
Fixed equipment costs	$
List sources and amounts of funds for total A&R project	
NIH sources and amounts	Sources and amounts other than NIH
Other Information	
Total gross square meters/feet of floor area in A&R proposal	
Estimated cost per gross square meter/foot excluding fixed equipment	
Total net square meters/feet of floor area in A&R proposal	
Estimated cost per net square meter/foot, excluding fixed equipment	

Real Property Management Standards

General

Real property constructed under an NIH grant-supported project is subject to the requirements of 42 CFR Part 52b and the provisions of 45 CFR 74.30 through 74.32 and 74.37 or 92.31, as applicable, regarding use, transfer of title, and disposition, unless alternate requirements are specified in the governing statute. Statutory provisions may specify alternate requirements for the length of the grantee's accountability obligations, the Federal right of recovery, or waivers. For example, the governing statute for a construction grant program may contain usage and disposition requirements that are in addition to or different from the usage and disposition requirements of the governing regulations. To the extent statutory provisions differ from the requirements of 42 CFR Part 52b and/or 45 CFR Part 74 or 92, including those described in this subsection, the statutory provisions, as reflected in the terms and conditions of the award, apply.

Real property constructed or renovated with NIH grant support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the grantee, except as expressly authorized in writing by NIH. If the grantee defaults in any way on a mortgage, the grantee shall immediately notify the GMO by telephone and in writing. If the mortgagor intends to foreclose, the grantee 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 in the case of default, the grantee shall pay NIH an amount equal to the share of the sales proceeds otherwise due the grantee multiplied by the NIH share of 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.

Use and Disposition

NIH construction awards generally require that a facility be used for biomedical or behavioral research as long as needed for that purpose. NIH defines this period as 20 years from the date of beneficial occupancy unless another period is prescribed by statute. During that time, the grantee shall comply with applicable disposition requirements. If, during the required usage period, the facility is no longer used for the original intended purpose and NIH did not provide prior approval for an alternate use, NIH may recover its share. NIH will monitor grantee compliance with these requirements for the duration of the required usage period. After the required usage period, the grantee has no further accountability to NIH concerning the use of the property or any sales proceeds.

For disposition of property acquired on an amortized acquisition basis, the formulas in 45 CFR 74.32 and 92.31 do not apply in determining the Federal share. In cases of amortized acquisition, the Federal share will be determined by multiplying the amount of mortgage principal already repaid at the time of disposition by the average Federal participation (taken from the FSR) plus the increase in value over the purchase price multiplied by the average Federal participation plus the Federal participation in the down payment. The computation of the Federal share of real property acquired with long-term debt financing must 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.

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).

Notice of Federal Interest

To protect the Federal interest in real property that has been constructed or has undergone major renovation with NIH grant funds, grantees shall record a NFI in the appropriate official records of the jurisdiction in which the property is located. The time of recordation shall be when construction or renovation begins. Fees charged for recording the NFI may be charged to the grant (see "Allowable and Unallowable Costs and Activities" in this section).

Insurance Requirements

Immediately upon completion of construction, a nongovernmental grantee 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 the facility over to the grantee (e.g., the date of the final acceptance of the building) or the date of beneficial occupancy, whichever comes first.

If title to real property acquired with NIH grant funds vests in the grantee, 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 in the construction of real property 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 grantee 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 grantee may provide evidence satisfactory to the NIH awarding office, 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 grantee is given land by the State, if the State recently acquired the land in a land swap transaction, the grantee should obtain title insurance. However, if the State has owned the land for a considerable period of time, title insurance would not be necessary; a copy of the State documents giving the land to the grantee would be sufficient. If the grantee 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 from risk of partial and total physical destruction. When the Federal participation in the construction or renovation of real property 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 (usually 20 years) (see "Real Property Management Standards—Use and Disposition" in this section). 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 construction or renovation. The grant account will not remain active for this purpose.

Governmental grantees may follow their own insurance requirements. Federally owned property provided to a grantee for use need not be insured by the grantee.

Within 5 days of completion or beneficial occupancy, the grantee shall submit, to the GMO, a written statement signed by the AOO assuring that the grantee has purchased the required insurance policies on the NIH-funded facility and will maintain the insurance coverage at the full appraised value of the facility throughout the period of Federal interest as specified in the NGA.

The NIH awarding office may waive one or both of the requirements above if the grantee shows that it is effectively self-insured against the risks involved. The term "effectively self-insured" means that the grantee 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 grantee claims self-insurance, the grantee must provide to NIH assurance that it has sufficient funds available to replace or repair the facility or to satisfy all liens. This certification should state the source of the funds, such as the organization's endowment or other special funds set aside specifically for this purpose.

RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS[17]

General

This section includes general information about and application requirements for Kirschstein-NRSA individual fellowships and institutional research training grants. For Kirschstein-NRSA individual fellowships, this section includes coverage of the public policy requirements concerning human subjects, including data safety and monitoring requirements; inclusion in research of women, minorities, and children; human embryonic stem cells; animal welfare; recombinant DNA molecules and human gene transfer; responsible conduct of research; and acknowledgment of funding. The detailed coverage of these public policy requirements is found in Subpart A. For institutional research training grants, other requirements of Subpart A also apply; this section of Subpart B mentions the applicable requirements with cross-references to Subpart A.

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 public and non-profit private entities. The legislation requires 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, research

[17] In 2002, the National Research Service Awards program was renamed the Ruth L. Kirschstein National Research Service Awards program as a tribute to Dr. Kirschstein's years of exceptional service to the nation.

training, health-related teaching, or any combination of these activities. (See "Payback Reporting Requirements" in this section). The regulations at 42 CFR Part 66 apply to these awards.

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 office should be contacted if there are any questions concerning compliance. (See "Public Policy Requirements and Objectives—Civil Rights" for detailed requirements.)

Individual Fellowships

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 and behavioral research agenda. 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. Some specialized individual pre-doctoral fellowships (F31 and F30), Senior Fellowships (F33), and other unique fellowship programs also are provided under this authority. For individual predoctoral fellowships, NIH ICs have differing requirements. Thus specific PAs and RFAs 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 except FIC and NLM award Kirschstein-NRSA fellowships. FIC and NLM have unique funding authorities for fellowships that are not under the Kirschstein-NRSA authority.

Eligibility

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 fit these areas will be returned. Research training of physicians has been increasingly emphasized. 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 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.

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 health professional degrees or to support the clinical portion of residency training. Research trainees in clinical areas are expected to devote full time to the proposed research training and to confine clinical duties to those that are part of the research training.

Degree Requirements

Predoctoral training. Individuals must have received, as of the activation date of their Kirschstein-NRSA pre-doctoral fellowship award, a baccalaureate degree and must be enrolled in and training at the postbaccalaureate level in a program leading to the award of a Doctor of Philosophy of Science (Ph.D. or Sc.D.) or a combined clinical degree and Ph.D. degree such as M.D./Ph.D.

Postdoctoral training. Before a Kirschstein-NRSA postdoctoral fellowship award can be activated, individuals must have received a Ph.D., M.D., D.O., D.C., D.D.S., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.S., N.D., Pharm.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign institution. Also acceptable is a statement by an AOO of the degree-granting institution that all degree requirements have been met.

Senior fellows. As of the beginning date of their award, senior fellows must have received a doctoral degree (as specified in "General—Degree Requirements—Postdoctoral Training") and must have had 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 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. Health professionals may use some of their time in clinical duties as part of their research training. More information on the senior fellowship program can be found in the NIH Kirschstein-NRSA Senior Fellows (F33) program announcement available on the NIH website at http://grants.nih.gov/training/nrsa.htm - fellowships.

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 people, 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 Alien Registration Receipt Card (I-551) or other legal verification of such status. For example, if an individual has the proper validation on his/her 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 applicant selected to receive an award must provide a notarized statement of admission for permanent residence prior to award.

Applicants who have been lawfully admitted for permanent residence, i.e., have an Alien Registration Receipt Card or other legal verification of such status, should check the Permanent Resident box in the citizenship section on the face page of the fellowship application. Applicants who have applied for and have not yet been granted admission as a permanent resident should check the same box, but should write in the word "pending."

Individuals on temporary or student visas are not eligible to apply for Kirschstein-NRSA individual fellowships.

Sponsorship

General. Before submitting a Kirschstein-NRSA individual fellowship application, the 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 the NIH intramural programs, other Federal laboratories, and units of State and local governments. The applicant's sponsor should be an active investigator in the area of the proposed research who will directly supervise the candidate'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 applicants proposing training at their doctoral institution or at the institution where they have been training for more than a year must document thoroughly the opportunity for new training experiences designed to broaden their scientific backgrounds.

Foreign sponsorship. An individual may request support for training abroad. In such cases, the 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 will be considered for funding only when the scientific advantages are clear.

NIH Employees

Both civil service employees and PHS commissioned officers at NIH 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. The employee's supervisor must disassociate himself/herself from the review and award process.

Successful NIH applicants for predoctoral or postdoctoral fellowship awards must either resign from NIH or take LWOP before activating the award. (There is no obligation or commitment by NIH or the fellow for future employment at NIH upon termination of the fellowship.)

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 applicant's branch of the military service should submit a letter endorsing his/her 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 awardees is not allowed.

Application Requirements and Receipt Dates

Application

Each applicant must submit an application using the PHS 416-1. At least three letters of reference on his or her behalf also must be submitted. The major emphasis of the application should be the research training experience and broadening of scientific competence. The application must include the sponsor's Facilities and Commitment Statement. By signing the face page of the application, the applicant indicates that he or she has read the payback information and will meet any payback provisions required under the law as a condition for accepting the award.

Applicants and sponsoring institutions must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data safety and monitoring requirements; the humane care and use of live vertebrate animals; the inclusion of women, minorities and children in study populations; human embryonic stem cells; and recombinant DNA and human gene transfer research. (For a complete list of applicable requirements, see Exhibit 2, "Public Policy Requirements and Objectives" in Subpart A).

If an application is submitted in response to an IC-specific PA or RFA, the applicant should identify the number of the PA or RFA on the face page. This information will be used as a guide in the application assignment process.

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.

Application availability. Application forms and instructions are available from the NIH website at http://grants.nih.gov/grants/forms.htm. Application form pages are available in pdf-fillable and rtf formats. Further assistance is available from GrantsInfo at 301-435-0714 or GrantsInfo@nih.gov.

Receipt Dates

Kirschstein-NRSA individual fellowship applications undergo a review process that takes 5 to 8 months. The appendix to this section shows the annual schedule for application receipt, review, and award.

Review

Each new and competing continuation application will be evaluated for scientific merit by an NIH SRG. Review criteria include the candidate's previous academic and research performance and the potential to become an important contributor to biomedical, behavioral, or clinical science; the quality of the training environment and the qualifications of the sponsor; the merit of the scientific proposal and its relationship to the candidate's career plans; and the value of the proposed fellowship experience. In determining scientific merit and the priority score, when applicable, the SRG also considers plans for the protection of human subjects from research risks; the inclusion of women, minorities, and children in research; and the care and use of vertebrate animals in the proposed research.

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.

Notification of Action

Shortly after the initial review meeting, each candidate receives a mailer that includes the SRG recommendation/priority score and the name and telephone number of a PO in the assigned NIH IC. A copy of the summary statement is automatically forwarded to the applicant as soon as possible.

The PO will 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 to the SRA of the SRG. An NRFA will be issued to applicants selected for funding.

Period of Support

No fellow 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.

Any exception to the maximum period of support requires a waiver from the NIH awarding office based on review of a justification from the individual and sponsoring institution. The fellow must make the request in writing to the NIH awarding office. The fellow's sponsor and an AOO must endorse the request. 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, may anticipate favorable consideration of a request for waiver of the time limitation. This action is contingent upon an assurance of the recipient's good academic standing and justified need for the exception.

- *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.

Full-Time and Part-Time Training

All fellows are required to pursue their research training full time, normally defined as 40 hours per week or as specified by the sponsoring institution in accordance with its own policies. Under unusual or pressing personal circumstances, a fellow may submit a written request to the NIH awarding office to permit less than full-time training.

Written requests for part-time training will be considered case by case and must be approved by the NIH awarding office in advance of each budget period. The circumstances requiring part-time training might include medical conditions, disability, or pressing 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 for responsibilities associated with the fellow's position at the sponsoring institution.

Each written request from the fellow must be countersigned by the sponsor and an AOO and must include documentation supporting the need for 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. Individuals may not engage in Kirschstein-NRSA support for less than 50 percent effort. Individuals unable to devote 50

percent effort will be required to take a leave of absence from Kirschstein-NRSA fellowship support.

NIH will issue a revised NRFA and the stipend will be prorated during 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.

Initiation of Support

Process

The NIH IC will notify the individual of the intention to make an award and confirm the plans for the start of fellowship support. The NRFA allows the individual to begin the fellowship immediately on or after the issue date, but permits up to 6 months for the individual to make final arrangements, such as the completion of degree requirements, final coordination with the sponsor, and, if necessary, a move to the sponsoring institution. The fellow must start the period of training under the award by the latest activation date as shown on the NRFA, i.e., 6 months from the award issue date. The activation period may be extended in unusual circumstances. Written requests for extensions should be submitted by the fellow, and must be countersigned by the sponsor and the AOO.

The Activation Notice must be submitted to the NIH awarding office as of the day the fellow 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 section. 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 office. 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.

Individual fellowship support generally is approved for consecutive years of training. The initial award usually is 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, he or she should notify the institution's business office, the sponsor, and the NIH awarding office immediately, in writing. NIH will make any necessary adjustments in the stipend and other costs, including the institutional allowance.

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 office through NIH's OFM. Reimbursement to the fellow for appropriate expenditures from the institutional allowance also is coordinated by the NIH awarding office and paid through OFM.

Foreign. Fellows training at foreign sites receive stipends directly from NIH's OFM. However, the institutional allowance is awarded to and disbursed by the sponsoring institution.

Allowable and Unallowable Costs

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, and NIH will issue a revised NRFA. No departure from the standard stipend provided by NIH under the fellowship may be negotiated by the sponsoring institution with the fellow.

Stipend Levels

Stipend levels are updated nearly every year. When increases are approved, they are published in the *NIH Guide for Grants and Contracts*. Current levels are posted at http://grants.nih.gov/training/nrsa.htm. The NIH awarding office will adjust fellowship awards on their anniversary dates to include the currently applicable stipend amount.

General information related to stipends follows:

- *Predoctoral.* One stipend level is used for all pre-doctoral candidates, regardless of the level of experience.

- *Postdoctoral.* The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience when the award is issued. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the fellow must be paid at that level for the entire grant year. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.

- *Senior fellows.* The amount of the Kirschstein-NRSA stipend to be paid must be commensurate with the base salary or remuneration that the individual receiving the award would have been paid by the institution with which he or she has permanent affiliation on the 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.

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 institutions, are published in the *NIH Guide for Grants and Contracts*. They also are available on the NIH website at http://grants.nih.gov/training/nrsa.htm#fellowships. For postdoctoral fellowships, costs for tuition and fees, where appropriate, will be awarded independent of the institutional allowance. (See "Allowable and Unallowable Costs—Tuition and Fees" in this subsection for details on tuition reimbursement.)

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.

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 NRFA will be revised and the balance must be refunded to NIH.

For fellows at Federal training sites, the NIH awarding office authorizes the expenditure of the allowance. Payment is made through NIH's OFM.

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 office and disbursed by OFM.

- *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 current 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 people 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.

- *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.

Tuition and Fees

Currently NIH offsets the combined cost of tuition and fees for Kirschstein-NRSA postdoctoral fellows at the following rate: 100 percent of all costs up to $3,000 and 60 percent of costs above $3,000. Any change in this formula is published in the *NIH Guide for Grants and Contracts*.

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 it is part of the institutional allowance.

For predoctoral fellows, the award of tuition and fees (including health insurance) may vary depending on the policy of the NIH awarding office. Specific programmatic guidelines should be consulted for guidance.

When tuition, fees, and insurance are awarded as a separate budget item, these funds may not be rebudgeted into any other budget category without written prior approval from the NIH awarding office.

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.

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, FICA, workman's compensation, and unemployment insurance).

Supplementation of Stipends, Compensation, and Other Income

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 does not require any additional obligation from 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 this subsection.

Compensation

NIH recognizes that Kirschstein-NRSA fellows may seek part-time employment incidental to their training program to offset further their expenses. 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—Salaries and Wages—Compensation of Students." 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 agreement. 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 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.

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.

Concurrent Benefits

A Kirschstein-NRSA individual fellowship may not be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the Kirschstein-NRSA award.

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. Postdoctoral fellows also may be eligible to participate in the NIH Loan Repayment Program. Information on this program is available at http://www.lrp.nih.gov/.

Taxability of Stipends

Section 117 of the Internal Revenue Code applies to the tax treatment of scholarships and fellowships. Degree candidates may exclude from gross income (for tax purposes) any amount used for course 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 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.

Form 1099

Although stipends are not considered salaries, this income is still 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 income received and 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 as income. NIH will issue a Form 1099 for each fellow training at a Federal or foreign laboratory and receiving a stipend check from the U.S. Treasury.

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 rtf formats at http://grants.nih.gov/grants/forms.htm. The NIH awarding office may provide copies of applicable forms with the NRFA or reference this website in the NRFA.

Activation Notice

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 AOO, 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 office.

For Kirschstein-NRSA fellows paid directly by NIH, the Activation Notice is required at the start of each award year. 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 office.

For fellows whose stipend is paid through the institution, 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 training. Furthermore, if the individual does not begin research training on the day indicated, the institution must notify the NIH awarding office immediately. Competing continuation awards must be activated on the day following the end of the last budget period of the previous award.

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 section.

No Payback Agreement is required for predoctoral fellows.

Termination Notice

The Ruth L. Kirschstein National Research Service Award Termination Notice (Form PHS 416-7) (along with the Activation Notice and the NRFA) 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 office before the scheduled termination date. For early terminations, the completed form will be required immediately upon receipt of notification from the fellow or an AOO. The lack of timely and accurate information on this form could adversely affect the payback process. For additional information on early termination, see "Changes in the Project" in this section.

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.

Progress Reports

Progress reports must be submitted for non-competing continuation support in accordance with the instructions accompanying the Progress Report for Continuation Support (Form PHS 416-9). Progress report forms and instructions are available from the NIH website at http://grants.nih.gov/grants/forms.htm. Report form pages are available in pdf-fillable and rtf formats. Inadequate or incomplete progress reports may be returned to the fellow for revision and may result in a delay of continued support. For Kirschstein-NRSA individual fellowship awards, the final progress report is required as part of the Termination Notice.

Financial Reporting

An annual or final FSR is not required on Kirschstein-NRSA individual fellowship awards.

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 office 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 initial institution may be requested to continue to pay the stipend until the end of the current year. Disposition of the institutional allowance is negotiable between the two sponsoring institutions. No Activation Notice is required from the new sponsoring institution.

Transfers involving Federal or foreign sponsoring institutions require unique administrative procedures and approvals. Because each transfer varies depending on individual circumstances, the sponsoring institution should contact the NIH awarding office 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 office to ensure that the training continues to fall within the scientific area of the original peer-reviewed application.

When the sponsor is going to be absent for more than 3 months, an interim sponsor must be named by the institution and approved in writing by the NIH awarding office.

Other Terms and Conditions

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.

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 office in response to a written request from the sponsor, countersigned by an AOO. Sick leave may be used for medical conditions related to pregnancy and childbirth.

Parental leave. Kirschstein-NRSA fellows may receive stipends for up to 30 calendar days of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee or sponsoring institution have access to paid leave for this purpose. 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 30 calendar days of parental leave, must seek approval for an unpaid leave of absence. Approval for a leave of absence must be requested in advance from the NIH awarding office. Fellows must provide a letter of support from the sponsor, countersigned by an AOO, and must advise the NIH awarding office of the dates of the leave of absence. Upon approval of the request, the NIH awarding office will issue a revised NRFA extending the ending date of the current budget 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.

During a leave of absence, documentation to suspend the award and/or the accrual of service for calculating the payback obligation must be completed by the sponsoring institution. When the fellowship is eventually terminated, the leave of absence must be clearly documented on the Termination Notice.

Termination

NIH may terminate a Kirschstein-NRSA individual fellowship before its normal expiration 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 for cause, 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 recipient. The NIH awarding office must be notified immediately if a sponsoring institution wants to terminate an individual fellow or the fellow decides to terminate training before the scheduled expiration date.

If a Kirschstein-NRSA fellowship is terminated early, the stipend must be prorated according to the amount of time spent in training, and the NRFA will be revised. The balance of any institutional allowance (at least one-half) must be refunded if the training has been for 6 months or less.

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 potential commercialization of inventions. 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 office 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 "Public Policy Requirements and Objectives—Availability of Information—Acknowledgment of Federal Funding."

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 office. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce them, translate them, publish them, and use and dispose of them, and to authorize others to do so for Federal government purposes.

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 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 actually reduced to practice during the period of the fellowship.

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.

Public Policy Requirements and Objectives

Human Subjects

Kirschstein-NRSA individual fellowship awards involving use of human subjects must comply with the requirements for their protection (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects"). For additional information on human subjects requirements, refer to the Kirschstein-NRSA individual fellowship application instructions (http://grants.nih.gov/grants/funding/416/phs416.htm) or contact OHRP (see contact information in Part III).

Monitoring Plan and Data and Safety Monitoring Board

Research involving clinical trials must include provisions to ensure the safety of participants and the validity and integrity of the data. A monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for monitoring and how adverse events will be reported to IRBs, NIH, and FDA. The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial.

NIH specifically requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risks to the subject and, generally, for Phase III clinical trials. Although Phase I and Phase II clinical trials also may use DSMBs, smaller clinical trials may not require this type of oversight, and alternative monitoring plans may be appropriate.

Fellows also should refer to the *NIH Policy for Data and Safety Monitoring* at http://grants.nih.gov/grants/guide/notice-files/not98-084.html, "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Data and Safety Monitoring" in Subpart A, and the instructions in the PHS 416-1 application.

Inclusion of Women and Minorities in Clinical Research

Pursuant to the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), NIH requires that women and members of minority groups and their subpopulations be included in all

NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research (see "Public Policy Requirements and Objectives—Requirements for Inclusiveness in Research Design").

Individuals proposing clinical research should read *the NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research*–Amended, October 2001, available on the NIH website at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

Inclusion of Children as Participants in Research Involving Human Subjects

NIH policy requires that children (individuals under the age of 21) be included in all human subjects research conducted or supported by NIH, unless there are scientific and ethical reasons not to include them (see "Public Policy Requirements and Objectives—Requirements for Inclusiveness in Research Design"). Individuals proposing research involving human subjects should read *NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects*, available on the NIH website at http://grants.nih.gov/grants/funding/children/children.htm.

Human Embryonic Stem Cell Research

Criteria for Federal funding of research on hESC can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the individual's responsibility to provide the official NIH identifiers for the hESC lines to be used in the proposed research (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services"). Applications that do not provide this information will be returned without review.

Responsible Conduct of Research

Kirschstein-NRSA individual fellowship applicants must include, as part of their application, plans for obtaining instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency, and duration of instruction. The amount and nature of faculty participation must be described.

While NIH does not establish specific curricula or formal requirements, applicants are encouraged to creatively tailor a plan to meet their own needs in relation to the proposed research training. It may include participating in formal activities, such as established courses (credit or noncredit) either as an instructor or a student, or informal activities, such as discussion groups. Possible coverage could include conflict of interest, responsible authorship, policies for handling misconduct, data management, data sharing, policies for the use of animals and/or human subjects, and organizational (rather than individual) responsibilities for scientific integrity.

No award will be made if an application lacks this component.

Vertebrate Animals

Kirschstein-NRSA individual fellowship awards involving use of vertebrate animals must comply with the requirements for their protection specified in "Public Policy Requirements and Objectives—Requirements Affecting the Right and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Animal Welfare." For additional information on vertebrate animals, refer to the Kirschstein-NRSA individual fellowship application instructions or contact OLAW (see contact information in Part III).

Recombinant DNA Molecules and Human Gene Transfer Research

Individuals receiving Kirschstein-NRSA fellowship awards involving use of recombinant DNA molecules must comply with the requirements of the *NIH Guidelines for Research Involving DNA Molecules* (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—NIH Guidelines for Research Involving Recombinant DNA Molecules and Human Gene Transfer Research"). The NIH Guidelines, available from NIH's OBA (see Part III), should be consulted for complete requirements for the conduct of projects involving recombinant DNA techniques. A copy of the NIH Guidelines is available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html.

Institutional Research Training Grants

General

NIH will award Kirschstein-NRSA institutional research training grants (T32, T34, and T35) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the institution, who are training for careers in specified areas of biomedical, behavioral, and clinical research. The purpose of the Kirschstein-NRSA program is to help ensure that a diverse and highly trained workforce is available in adequate numbers and in the appropriate research areas and fields to carry out the nation's biomedical and behavioral research agenda. The Kirschstein-NRSA program supports 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.

Eligibility

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 PHS

398 and appropriate instructions (see "Application Requirements and Receipt Dates" in this subsection).

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 fit 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 or behavioral research with the primary objective of developing or extending their research skills and knowledge in preparation for a research career.

Training Program Director

The training PD 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 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 program. In selecting trainees, the PD must make certain that individuals receiving support meet the eligibility requirements set forth in this subsection.

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, devoting at least 40 hours per week to the program. During the 40 hours per week required for research training, research trainees who also are training as clinicians must devote their time to the research training and must confine clinical duties to those that are an integral part of the research training experience.

Degree Requirements

Predoctoral Training

Predoctoral research training is for individuals who have a baccalaureate degree and are enrolled in a doctoral program leading to either a Ph.D., a comparable research doctoral degree, or a combined clinical degree and Ph.D, such as M.D./Ph.D. Students enrolled in health-professional programs that are not part of a formal, combined program (i.e., M.D./Ph.D.), and who wish to postpone their professional studies to gain research experience, also may be appointed to a Kirschtein-NRSA institutional research training grant. Predoctoral research training must emphasize fundamental training in areas of basic biomedical and behavioral sciences.

Postdoctoral Training

Postdoctoral research training is for individuals who have received a Ph.D., D.V.M., D.D.S., M.D., or comparable doctoral degree from an accredited domestic or foreign institution. Research training at the postdoctoral level must emphasize specialized training to meet national research priorities in the biomedical, behavioral, or clinical sciences.

Kirschstein-NRSA institutional research training grants are a desirable mechanism for the postdoctoral training of physicians and other health professionals who may have had extensive clinical training but limited research experience. For such individuals, the training may be a part of a research degree program. In all cases, health-professional postdoctoral trainees are to engage in at least 2 years of research, research training, or comparable experiences beginning at the time of appointment, since the duration of training has been shown to be strongly correlated with post-training research activity.

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 *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 or behavioral 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 in a program leading to a clinical doctorate or a masters or clinical 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 for approval at the time of award. 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.

Prebaccalaureate Training

NIH offers two distinct programs for prebaccalaureate training under the auspices of the Kirschstein-NRSA undergraduate support mechanism (T34). Both programs are designed to support students from institutions with a substantial minority enrollment.

NIGMS administers the MARC U*STAR program. This program is designed to support selected junior/senior undergraduate honors students at baccalaureate colleges and universities.

NIGMS recognizes that there are differences in organizational environments and missions. Therefore, the emphasis of this program is on the specific objectives and measurable goals that the applicant institution sets.

Information about the program is available at
http://www.nigms.nih.gov/funding/trngmech.html#ustar or through the following:

MARC Program Branch, NIGMS
Room 2AS.37D
45 Center Drive MSC-6200
Bethesda, MD 20892-6200

Telephone: 301-594-3900
Fax: 301-480-2753
E-mail: tolivera@nigms.nih.gov

NIMH administers the COR Program. The intent of this program is to provide focused undergraduate research and research training experiences in scientific disciplines related to mental health. An applicant institution (a 4-year college or university) must propose a 2-year COR Honors Undergraduate Program for which 6 to 10 highly talented third- and fourth-year undergraduate students will be selected. Students will be provided with mentored research training experiences designed to stimulate their entry into advanced research training programs leading to the doctoral-level or M.D. research career degrees. For more information on this program, contact:

COR Program
Office for Special Populations/NIMH
6001 Executive Blvd.
Suite 8125
MSC-9659
Bethesda, MD 20892-9659

Telephone: 301-443-2847
Fax: 301-443-8022
E-mail: rmays@mail.nih.gov

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 people, 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 Alien Registration Receipt Card (I-551) or other legal verification of such status. For example, if an individual has the proper validation on his/her passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the grantee'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 on temporary or student visas are not eligible for Kirschstein-NRSA support.

Application Requirements and Receipt Dates

Application

The application for Kirschstein-NRSA institutional research training grants is the PHS 398, which contains special instructions for those grants. Application forms, instructions, and related information may be obtained from http://grants.nih.gov/grants/forms.htm. For further assistance, contact GrantsInfo (telephone: 301-435-0714; e-mail: GrantsInfo@nih.gov).

Receipt Dates

Some NIH ICs receive training grant applications three times each year; however, most ICs have one receipt date only. Information on IC-specific receipt dates is available in the *NIH Guide for Grants and Contracts* in the NIH-wide T32 PA or in RFAs issued by the individual NIH ICs. For a list of the standard receipt dates and review cycle, see the appendix to this section. (Also see http://grants.nih.gov/training/nrsa.htm#inst).

Applicants are encouraged to contact the appropriate NIH staff before preparing and submitting an application. Applications (except those assigned to NIGMS, NICHD, NEI, NIDCR, or NINR) for funding requesting $500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within one of the NIH ICs who has agreed to accept assignment of the application.

Special Program Considerations

The primary objective of the Kirschstein-NRSA program is to prepare qualified individuals for careers that have a significant impact on the Nation's research agenda. Within the framework of the program's longstanding commitment to excellence and projected need for investigators in certain areas of research, institutions must attempt to recruit individuals from racial or ethnic groups underrepresented in the biomedical and behavioral sciences. The following groups are ones that nationally are underrepresented in biomedical and behavioral research: African Americans, Hispanic Americans, Native Americans, Alaskan Natives, and Pacific Islanders. NIH's requirements for minority recruitment and retention are described in "Review—Minority Recruitment Plan" in this subsection.

NIH also considers the duration of training and the transition of trainees to other support mechanisms. 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 PDs 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 PDs also should encourage postdoctoral trainees to apply for Kirschstein-NRSA individual postdoctoral fellowships (F32) or mentored career

development awards (K awards). When reviewing Kirschstein-NRSA institutional research training grant applications, peer reviewers will examine the training record to determine the average duration of training appointments for health-professional postdoctoral trainees and whether there is a history of transition to individual support mechanisms.

Studies also have shown that health professional trainees that train in combined programs with postdoctoral researchers with intensive research experience are more likely to apply for and receive research grant support. Programs 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 indicate whether both health professional trainees and trainees with research doctorates will be included in the training program.

Training PDs also are encouraged to develop methods for ongoing evaluation of the quality of the training program. Although the T32 application process requires extensive career-tracking information, it often is useful to obtain more timely feedback. NIH encourages PDs to develop plans to obtain feedback from current and former trainees to help identify weaknesses in the training program and to provide suggestions for program improvement. Applicant institutions are encouraged to include a description of these plans in competing applications.

Review

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.

Applications for Kirschstein-NRSA institutional research training grants will be evaluated using criteria such as the following:

- Past research training record of both the program and the designated preceptors.
- Objectives, design, and direction of the research training program.
- Caliber of preceptors as researchers, including successful competition for research support.
- Quality of the organizational training environment for NRSA-supported trainees and relationship of the NRSA program to the broader training program, if appropriate. This includes the level of organizational commitment, quality of the facilities, availability of appropriate courses, and the availability of research support.
- Quality of the applicant pool and the selection of individuals for appointment to the training program, including an assessment of the racial and ethnic diversity of the trainee

pool. The assessment will take into account described recruitment and retention and the availability of individuals from underrepresented groups within the relevant pool of applicants.

- Record of the research training program in retaining health-professional postdoctoral trainees for at least 2 years.

In addition, when applicable, the concomitant training of health-professional postdoctorates (e.g., individuals with the M.D., D.O. or D.D.S. degree) with basic science postdoctorates (e.g., individuals with a Ph.D. or Sc.D. degree) or linkages with basic science departments will receive special consideration.

Applicants also are encouraged to consult the PHS 398 application instructions, the NIH T32 PA, and specific IC PAs for additional details.

Short-Term Research Training Positions

In addition to the overall programmatic criteria, applications that request short-term research training positions in conjunction with full-time positions will be assessed using specific criteria. The NIH T32 PA and/or specific IC PAs should be consulted for details.

Minority Recruitment Plan

The Kirschstein-NRSA institutional research training grant program must provide for the recruitment and retention of individuals from underrepresented minority groups including, but not limited to, African Americans, Hispanic Americans, Native Americans, Alaskan Natives, and Pacific Islanders. All competing applications for Kirschstein-NRSA institutional research training grants must include a specific plan to recruit minorities.

Competing continuation applications for Kirschstein-NRSA institutional research training grants also must include a detailed section on the outcomes of the minority recruitment plan proposed in the previous competing application. Information on successful and unsuccessful recruitment strategies must be included. The application also must include information on the racial/ethnic distribution of the following:

- Students or postdoctorates who applied for admission or positions within the department under the Kirschstein-NRSA institutional research training grant

- Students or postdoctorates who were offered admission to or a position within the department

- Students enrolled in the academic program related to the research training grant

- Students or postdoctorates appointed to the research training grant.

For trainees who were enrolled in the academic program, the application should include information about the duration of research training and whether those trainees have finished their training in good standing.

The success of efforts to recruit and retain minority trainees is a factor in the assessment of the quality of the trainee pool and thus will be included in the priority score. In addition, peer reviewers will evaluate the minority recruitment plan and accomplishments (for competing continuation applications) after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of minorities and whether the experience in recruitment during the previous competitive segment has been incorporated into the formulation of the plan for the next competitive segment.

If an application is received without a minority recruitment plan, or without a report on the previous competitive segment, the application will be considered incomplete and may be returned to the applicant without review.

The findings of the review group will be included in an administrative note in the summary statement. If the minority recruitment plan of the application is judged to be unacceptable, funding will be withheld until a revised plan 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.

Information on the recruitment and retention of underrepresented minority trainees 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.

Training in the Responsible Conduct of Research

All Kirschstein-NRSA institutional research training grant applications must include a description of the formal and informal activities related to instruction in the responsible conduct of research planned for the proposed research training program. In addition, NIH encourages institutions to provide instruction in the responsible conduct of research to all individuals in a training program or department, regardless of the source of support.

Every prebaccalaureate, predoctoral, and postdoctoral Kirschstein-NRSA trainee must receive instruction in the responsible conduct of research. Applications must describe a program to provide formal or informal instruction in research integrity and/or the responsible conduct of research, as follows:

- Although NIH does not establish specific curricula or formal requirements, all programs are strongly encouraged to consider instruction in the following areas: conflict of interest, responsible authorship, policies for handling misconduct, data management, data sharing, and policies regarding the use of human and animal subjects. Within the context of training in scientific integrity, it also is beneficial to discuss the mutual responsibilities of the institution and the trainees participating in the program.

- Plans must address the subject matter of the instruction, the format of the instruction, the degree of faculty participation, trainee attendance requirements, and the frequency of instruction. The rationale for the proposed plan of instruction must be provided.

- Information on the type of instruction provided, topics covered, and other relevant information, such as attendance by trainees and faculty participation, must be included in future competing continuation applications.

Applications without plans for instruction in the responsible conduct of research will be considered incomplete and may be returned to the applicant without review.

NIH SRGs will assess the applicant's plans on the basis of the appropriateness of topics, format, amount and nature of faculty participation, and frequency and duration of instruction. The plan will be discussed after the overall determination of merit, so that the quality of the plan will not be a factor in the determination of the priority score. Plans will be judged as acceptable or unacceptable. The acceptability of the plan will be described in an administrative note on the summary statement. Regardless of the priority score, applications with unacceptable plans will not be funded until the applicant provides a revised, acceptable plan. The acceptability of the revised plan will be judged by staff members in the NIH IC.

Following initial 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 review group's comments on the plan for instruction in the responsible conduct of research.

Information on the nature of the instruction in the responsible conduct of science and the extent of trainee and faculty participation also must be provided in the progress report submitted as a prerequisite to receiving non-competing continuation support.

Notification of Action

Shortly after the initial review meeting, the PD will be sent a mailer that includes the SRG recommendation/priority score and the name and telephone number of a PO in the assigned NIH IC. The NIH IC automatically forwards a copy of the summary statement to the PD as soon as possible after receiving it from the SRG. The PD will be notified by the PO of the final review recommendation. An NGA will be issued for applications selected for funding. Any questions about initial review recommendations and funding possibilities should be directed to the named PO, not to the SRA of the SRG.

Period of Support

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; support for additional non-competitive years depends on satisfactory progress and availability of funds.

Trainees

Trainees under Kirschstein-NRSA institutional research training grants generally are appointed for full-time 12-month continuous periods. An appointment or reappointment may not exceed 12 months without prior approval by the NIH awarding office. All trainees are required to pursue their research training full time, normally defined as 40 hours per week or as specified by the grantee in accordance with its own policies. Unless the NIH awarding office furnishes other instructions, the amount of the stipend, tuition, and fees for each full period of appointment must be obligated by the grantee 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 office and then usually only to complete a planned 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. Under unusual and pressing personal circumstances, a PD may submit a written request to the NIH awarding office to change a trainee appointment to less than full time. Such requests will be considered case-by-case and must be approved by the awarding office before the applicable budget period. The circumstances requiring the part-time training might include medical conditions, disability, or pressing 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, or clinical training, or for other responsibilities associated with the trainee's position at the organization. In each case, the written request must be countersigned by the trainee and an AOO and must include documentation supporting the need for 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 trainee intends to return to full-time training when that becomes possible and 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.

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 office based on review of a justification from the individual and the grantee organization. The

trainee must make the request in writing to the NIH awarding office. The trainee's PD and an AOO must endorse the request certifying the need for additional support. The request must specify the amount 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.

Initiation of Support

An NGA is issued to the grantee organization, normally 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 office.

At the time of the initial appointment and subsequent reappointment, the training PD must submit a Statement of Appointment to the NIH awarding office. In addition, a signed Payback Agreement must be submitted for each postdoctoral trainee who is in his/her 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 subsection 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 grantee organization directly to the trainee.

Allowable and Unallowable Costs

Policies included in the applicable cost principles and the NIHGPS govern the expenditure of all training grant funds, unless otherwise indicated in the NGA.

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 provided as a condition of employment with either the Federal government or the grantee organization. Stipends must be paid in accordance with established stipend levels. No departure from the standard stipend provided by NIH under the grant may be negotiated by the grantee 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 at http://grants.nih.gov/training/nrsa.htm.

Stipend levels are as follows:

- *Prebaccalaureate.* Two separate levels are provided for trainees: freshman/ sophomore or junior/senior.

- *Predoctoral.* One stipend level is used for all predoctoral trainees, regardless of the level of experience.

- *Postdoctoral.* The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience at the time of appointment. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the trainee must be paid at that level for the entire period of appointment. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.

Training-Related Expenses

Funds are provided to defray costs such as staff salaries, consultant costs, equipment, research supplies, staff travel, 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, the MARC U*STAR program, or the COR program.

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.

Trainee Tuition, Fees, and Health Insurance

Tuition, fees, and health insurance (self-only or family) are allowable trainee costs only if such charges are applied consistently to all people 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.

Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program and requires NIH awarding office prior approval. For all Kirschstein-NRSA institutional research training grant awards, this budget category (tuition, fees, and health insurance) is calculated at the following rate: 100 percent of all costs up to $3,000 and 60 percent of costs above $3,000. Tuition, fees, and health insurance are awarded as a lump sum that can be allocated (without the prior approval of the NIH awarding office) based on recipient needs.

Trainee Travel Costs

If requested by the grantee, the NIH awarding office 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. 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 grantee 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 grantee 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 office. Letters requesting such training may be submitted to the NIH awarding office at any time during the appointment period.

Short-Term Training Costs

The grantee 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.

Employee Benefits

Because Kirschstein-NRSA awards are not provided as a condition of employment with either the Federal government or the grantee, 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, and unemployment insurance).

Facilities and Administrative Costs

Grantees, other than State, local, or Indian tribal governments, will receive F&A costs at 8 percent of modified total direct costs (exclusive of tuition and fees, health insurance, and expenditures for equipment) rather than on the basis of a negotiated rate agreement. State, local, and Indian tribal government agencies are eligible for full F&A cost reimbursement. For this policy, State universities or hospitals are not considered governmental agencies.

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 office prior approval.
- *Trainee costs.* For rebudgeting purposes, trainee costs include funds awarded in the stipends or tuition/fees and health insurance 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 office. Unless otherwise restricted, rebudgeting into or within the stipends and tuition, fees, and health insurance categories is allowable without prior approval of the NIH awarding office.
- *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 office.

Stipend Supplementation, Compensation, and Other Income

Stipend Supplementation

Grantees may supplement stipends from non-Federal funds provided the supplementation is without obligation to 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" in this subsection. Under no circumstances may PHS funds be used for supplementation.

Student Compensation

NIH recognizes that trainees as students may seek part-time employment coincidental to their training program to further offset their expenses. 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—Salaries and Wages—Compensation of Students." 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 or laboratory assistance, are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. However, it is expected 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. 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 PDs must approve all instances of employment on research grants to verify that the circumstances will not detract from or prolong the approved training program.

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 award that provides a stipend or otherwise duplicates provisions of the Kirschstein-NRSA award.

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. Postdoctoral trainees also may be eligible to participate in the NIH Loan Repayment Program. Information about this program is available at http://www.lrp.nih.gov/.

Taxability of Stipends

Section 117 of the Internal Revenue Code applies to the tax treatment of scholarships and fellowships. Degree candidates may exclude from gross income (for tax purposes) any amount used for course 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 taxability of stipends in no way alters the relationship between Kirschstein-NRSA trainees and grantee 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 grantee 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.

Form 1099

Although stipends are not considered salaries, the income still is subject to Federal and, sometimes, State taxes. The grantee organization may report such income on IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the grantee organization will be responsible for annually preparing and issuing the IRS Form 1099 for trainees. Grantee organizations are not required to issue the Form 1099, but it is a useful form of documentation of income received and it serves as a reminder to the trainee that some tax liability may exist. Even if the grantee organization does not issue the Form 1099, trainees are required to report Kirschstein-NRSA stipends as income.

Carryover Authority

Kirschstein-NRSA institutional research training grants are included in expanded authorities (except for carryover of unobligated balances). In most cases, grantees must obtain awarding office prior approval to carry over funds; however, some NIH awarding offices have waived this requirement for training grants as well. The NGA for a Kirschstein-NRSA institutional research training grant will specify whether or not the grantee must obtain the prior approval of the awarding office to carry over funds.

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" for policies that govern the disposition and reporting of program income.

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 rtf formats at http://grants.nih.gov/grants/forms.htm. The NIH awarding office also may provide copies of applicable forms along with the NGA or reference this website in the award.

Statement of Appointment (Form PHS 2271)

The grantee must submit a PHS 2271 to the NIH awarding office before or at the start of each trainee's appointment or reappointment. If registered in the NIH eRA Commons, grantees may submit the PHS 2271 data electronically using the X-TRAIN application. More information on X-TRAIN is available at https://commons.era.gov/commons/.

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. An accurate Social Security Number should be included on the Statement of Appointment and all other documents. The PD 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 FSR.

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 to the NIH awarding office on an amended PHS 2271 at the time of the change.

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 office 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.

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 Reporting Requirements" in this section.

No Payback Agreement is required for predoctoral or prebaccalaureate trainees.

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 is responsible for submitting a Termination Notice for each trainee within 30 days of the end of the total period of support. The lack of timely and accurate information on this form could adversely affect the payback process.

Progress Reports

Progress reports must be submitted for non-competing continuation support in accordance with the instructions accompanying the progress report forms (PHS 2590). Progress report forms and instructions are available from the NIH website at http://grants.nih.gov/grants/forms.htm. Progress report form pages are available in pdf-fillable and rtf formats. Incomplete or inadequate progress reports may be returned for revision and may result in a delay of continued support.

Following completion or termination of a project period, the grantee must submit a final progress report to the NIH awarding office within 90 days after the end of grant support.

Financial Status Report

An annual FSR is required for all Kirschstein-NRSA institutional research training grant awards no later than 90 days after the close of each budget period. This report will document the financial status of the grant according to the official accounting records of the grantee 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 and tuition that extend beyond the budget period are carried over as unliquidated obligations. However, if the report covers the final budget period of the project period, it must have no unliquidated obligations and must indicate the exact balance of unobligated funds (see "Administrative Requirements—Monitoring—Reporting—Financial Reports" and "Administrative Requirements—Closeout—Final Reports").

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 office.

If the PD is expected to be absent more than 3 months, plans for the conduct of the program during his or her absence must be approved in writing by the NIH awarding office. Any proposed change of PD must be requested by the grantee organization and be approved in writing by the NIH awarding office 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 office 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.

Other Terms and Conditions

Leave

Vacations and holidays. Trainees may receive the same vacations and holidays available to individuals in comparable training positions at the grantee 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.

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 office in response to a written request from the training PD countersigned by an AOO. Sick leave may be used for the medical conditions related to pregnancy and childbirth.

Parental leave. Trainees may receive stipends for up to 30 calendar days of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee organization have access to paid leave for this purpose. Either parent is eligible for parental leave. The use of parental leave must be approved by the training PD.

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 30 calendar days of parental leave, must seek approval from the NIH awarding office for an unpaid leave of absence. Approval for a leave of absence must be requested in advance by the training PD and be countersigned by an AOO.

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 office at the beginning of the leave. Upon resumption of Kirschstein-NRSA support, the reappointment must be documented on another Statement of Appointment form.

Termination

NIH may terminate a Kirschstein-NRSA institutional research training grant before its normal expiration date if it determines that the grantee 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 for cause, NIH will notify the grantee 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 grantee.

An organization that wants to terminate a training grant before the scheduled termination date must notify the NIH awarding office immediately. In such cases, NIH will issue a revised NGA to specify the changed period of support and to show prorated trainee stipends, depending on the amount of time spent in training.

Publications and Sharing of Research Results

NIH supports the practical application and sharing of outcomes of funded research. Therefore, PDs 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 grantee organization should assist trainees in these activities, including the potential commercialization of inventions. 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 "Public Policy Requirements and Objectives—Availability of Information—Acknowledgment of Federal Funding."

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 the approval of the NIH awarding office. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce them, translate them, publish them, and use and dispose of them, and to authorize others to do so for Federal government purposes.

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 45 CFR 74.24(h) and in 37 CFR 401.1(b)).

Public Access to Research Data

As specified in 45 CFR 74.36(d), the public must be given access to research data (through FOIA) under specified circumstances. NIH guidance is available at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

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 grantee organization for disposition in accordance with NIH policy on program income (see "Administrative Requirements—Management Systems and Procedures—Program Income"). 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.

Public Policy Requirements and Objectives

Human Subjects

Kirschstein-NRSA institutional research training grants involving human subjects must comply with the requirements for their protection (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects"). 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 on the face page of 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.

For additional information on human subjects requirements, refer to the PHS 398 or contact OHRP (see Part III for contact information).

Monitoring Plan and Data and Safety Monitoring Board

Research involving clinical trials must include provisions to ensure the safety of participants and the validity and integrity of the data. A monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for monitoring and how adverse events will be reported to IRBs, NIH, and FDA. The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial.

NIH specifically requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risks to the subject and, generally, for Phase III clinical trials. Although Phase I and Phase II clinical trials also may use DSMBs, smaller clinical trials may not require this type of oversight, and alternative monitoring plans may be appropriate.

PDs and trainees also should refer to the NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html, "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Data and Safety Monitoring" in Subpart A, and the instructions in the PHS 398 application.

Inclusion of Women and Minorities in Clinical Research

It is NIH policy that women and members of minority groups and their subpopulations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research (see "Public Policy Requirements and Objectives—Requirements for Inclusiveness in Research Design"). This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). *NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research*, Amended, October 2001, is available on the NIH website at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

Inclusion of Children as Participants in Research Involving Human Subjects

NIH maintains a policy that children (individuals under the age of 21) must be included in all human subjects research conducted or supported by NIH, unless there are scientific and ethical reasons not to include them (see "Public Policy Requirements and Objectives—Inclusiveness in Research Design"). *NIH Policy and Guidelines on the Inclusion of Children as Participants in*

Research Involving Human Subjects is available on the NIH website at http://grants.nih.gov/grants/funding/children/children.htm.

Human Embryonic Stem Cell Research

Criteria for Federal funding of research on hESC can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the trainee to provide the official NIH identifiers for the hESC lines to be used in the proposed research (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—NIH Guidelines for Research Using Human Embryonic Stem Cells"). Applications that do not provide this information will be returned without review.

Vertebrate Animals

Kirschstein-NRSA institutional research training grants involving use of vertebrate animals must comply with the requirements for their protection (see "Public Policy Requirements and Objectives—Animal Welfare").

If the applicant organization has an approved Assurance of Compliance 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, on the face page of the application, the organization should check "Yes," include the animal welfare Assurance of Compliance 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 office.

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.

If the applicant organization does not have an approved Assurance of Compliance on file with OLAW or for additional information on vertebrate animals, refer to the PHS 398 or contact OLAW (see Part III).

Recombinant DNA Molecules and Human Gene Transfer Research

Institutions receiving Kirschstein-NRSA institutional research training grants involving use of recombinant DNA molecules must comply with the requirements of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—NIH Guidelines for Research Involving Recombinant DNA Molecules and Human Gene Transfer Research"). The NIH Guidelines, available from NIH's OBA (see Part III), should be consulted

for complete requirements for the conduct of projects involving recombinant DNA techniques. The NIH Guidelines are available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html.

Payback Reporting Requirements

General

The Kirschstein-NRSA legislation requires some recipients of support (fellows or trainees) to pay back the Federal government by engaging in health-related biomedical or behavioral research, including the direct administration or review of health-related research, health-related teaching, or any combination of these activities. See "Payback—Service Payback—Definitions" in this subsection for complete coverage of requirements.

The National Institutes of Health Revitalization Act of 1993, signed into law on June 10, 1993, included provisions in Section 1602 that substantially modified the service payback requirement for individuals supported by NRSA fellowships and research training grants.

An individual who was appointed to a research training grant or who had a fellowship award activated before June 10, 1993, is subject to the service payback provisions in effect at the time of the appointment or award.

Implementation

The incurrence of a payback obligation for an NRSA recipient is solely dependent upon when NRSA support was received.

Before August 13, 1981

Before August 13, 1981 (enactment of the Omnibus Reconciliation Act), a payback obligation existed for all prebaccalaureate, predoctoral, and postdoctoral support received.

Effective August 13, 1981

Effective August 13, 1981, a 12-month legislative allowance waiving payback obligation for the first 12 months of support was enacted for all predoctoral and postdoctoral trainees and fellows. This legislation provided that all trainees and fellows who were not in delinquent status on that date receive the allowance (this was retroactive to the beginning of the NRSA program). Individuals in delinquent status continued to have a payback obligation for all support received. This legislative change also eliminated the payback obligation for prebaccalaureate recipients.

Historically, short-term trainees supported by the T35 mechanism (NRSA short-term training) incurred no payback obligation. However, for short-term trainees supported within a T32 program, the periods of support accrued and ultimately counted toward the total NRSA support.

Effective June 10, 1993 (NIH Revitalization Act)

Predoctoral recipients. For predoctoral trainees beginning appointments and for predoctoral fellows activating awards on or after June 10, 1993, 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 with the 13th and subsequent months of postdoctoral support serving 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.

The requirements established by the Revitalization Act also provide that the 13th and subsequent months of postdoctoral Kirschstein-NRSA-supported research training will be used to discharge any prior postdoctoral Kirschstein-NRSA service payback obligation. See "Payback—Service Payback—Initiation of Payback Service" in this subsection for other requirements of the Act.

Short-Term Training

Any individual receiving support for predoctoral short-term training does not incur a payback obligation. Postdoctoral short-term training incurs a payback obligation. Any support accrues along with any subsequent 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.

Payback

Once a Termination Notice has been submitted and accepted, the NIH awarding office 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 PSC. PSC personnel are NIH's experts in Kirschstein-NRSA payback requirements. The PSC currently administers the payback activities of almost all of the NIH ICs and soon is expected to have this responsibility for all 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 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.

Definitions

For fulfilling the Kirschstein-NRSA service payback obligation, the following definitions apply:

- *Research.* Research is defined as an activity that involves designing experiments, developing protocols, and collecting and interpreting data. In addition, review of original research or administration of original research that includes providing scientific direction and guidance to research may be acceptable if a doctoral degree and relevant research experience is required for individuals filling such positions. Such research can be conducted in an academic, government, commercial, or other environment in either a foreign or domestic setting. In addition, when consistent with the cumulative amount, type, and frequency of research or research training experiences, functions that involve analytic or other technical activities conducted in direct support of research, as defined above, also will 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 activities.* This incorporates a broad range of activities related to the description, diagnosis, prevention, or treatment of disease from the most basic biomedical or behavioral research to the most applied or clinical research. Activities in 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.

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 child care or elder care responsibilities. It is not permissible for individuals otherwise engaged in full-time employment to engage in service payback activities at effort levels below 20 hours per week.

If less than 20 hours commitment per week is permitted, the total period of service obligation will be prorated. For example, an individual who owes 12 months of service and can devote only 10 hours per week to service payback activities due to a disability will be required to engage in

such service for 24 months. These exceptions are rare and must receive prior approval from the PSC.

Initiation of Payback Service

Initiation of payback service depends on when awards were made:

- *Support received before NIH Revitalization Act.* For predoctoral NRSA recipients who incurred a payback obligation from support received prior to June 10, 1993, payback service must be performed, or financial repayment made, following completion of NRSA support. No amount or type of activity before or during the period of NRSA support will satisfy the NRSA service payback obligation. However, payback service may be initiated immediately after termination of NRSA support if the research or teaching activities meet the criteria cited in "Payback Reporting Requirements—Payback—Service Payback—Definitions."

  For postdoctoral NRSA recipients who incurred a payback obligation from support received prior to June 10, 1993, continued postdoctoral NRSA support can be used to satisfy any previous postdoctoral payback obligation. However, continued postdoctoral NRSA support cannot be used to payback any obligation remaining from predoctoral support received before June 10, 1993.

- *Support received after NIH Revitalization Act.* Beginning with awards made under the authority of the NIH Revitalization Act (appointments on or after June 10, 1993), 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, training, or teaching averaging more than 20 hours per week.

    Trainees and fellows beginning appointments for the 13th and subsequent months of postdoctoral Kirschstein-NRSA support on or after June 10, 1993, will be engaging in service that also satisfies any postdoctoral NRSA service payback obligation incurred before June 10, 1993. Post-award service in non-Kirschstein-NRSA supported health-related research, training, or teaching is creditable toward any predoctoral or postdoctoral Kirschstein-NRSA service payback obligation.

Source of Funding

There is no restriction on the source of funds supporting an individual's service payback activity except that predoctoral payback activities must not be supported by Kirschstein-NRSA funds. An individual could be supported by a PHS grant or any non-Kirschstein-NRSA Federal or non-Federal source. Unpaid service also is permitted.

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").

Financial Payback

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" in this subsection), 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.

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 be accruing 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 termination of Kirschstein-NRSA support. For example, if during June 1998, OFM received an account reflecting January 31, 1996, as the termination date of NRSA support, the Federal government, lacking any documentation to the contrary, becomes entitled to financial payback effective February 1, 1998. The rate of interest applicable is determined based on the February 1, 1998, date, and the total NRSA obligation is required to be fulfilled by January 31, 2001.

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.

Extensions of Payback

The authorizing legislation and the implementing regulations (42 CFR Part 66) permit exceptions to certain requirements under the Act.

Extensions of the 2-Year Period to Initiate Payback

Frequently, an Annual Payback Activities Certification is returned requesting an extension of the 2-year period to initiate payback. Indication of valid plans to initiate payback soon after the 2-year grace period may be good reason to grant an extension.

Basis for Extensions or Break in Service

The Payback Service Center 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 his or her 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 such things as completing residency training, where clinical teaching or research are not an integral part of their training, or seeking employment that would fulfill the payback requirements.

Requests must be made in writing (separate letter or APAC) to the PSC, specifying the need for additional time and the length of the required extension.

Waiver

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.

Waiver Criteria

Requests for waivers should be made in writing to the PSC and should explain 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 might 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.

Certification of Payback Activities

Annual Payback Activities Certification (Form PHS 6031-1)

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 NIH 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 he or she was 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 his or her status. This process will continue annually until the individual's total payback obligation is satisfied.

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.

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 website at http://grants.nih.gov/grants/forms.htm.

National Health Service Corps

Occasionally, a Kirschstein-NRSA recipient may have been a NHSC scholar. Before October 26, 2002, legislation provided authority for holders of both awards to pay back the obligation of the two sources of support concurrently. Therefore, activities that qualified as Kirschstein-NRSA payback also served as payback for the NHSC obligation. However, no Kirschstein-NRSA legislative allowance is credited toward NHSC service The PSC monitors both obligations until they are both satisfactorily completed.

Effective October 26, 2002, the legislation was changed to eliminate concurrent payback. As a result, Kirschstein-NRSA recipients that also are NHSC scholars now 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 payback service.

Appendix
Receipt, Review, and Award Schedule

Ruth L. Kirschstein National Research Service Award Institutional Research Training Grants*			
	Review and award schedule		
Application receipt dates	Scientific merit review	Advisory Council review	Earliest award
January 10	June/July	September/October	December
May 10	October/November	January/February	April
September 10	February/March	May/June	July

Ruth L. Kirschstein National Research Service Award Individual Fellowships		
Application receipt dates	Initial review dates	Range of likely start dates
Fellowships other than minority and disability programs		
April 5	June/July	September/December
August 5	October/November	January/March
December 5	February/March	May/July
Minority and disability programs		
May 1	June/July	September
November 15	January/February	May

*Several NIH ICs use only one or two of the receipt dates for Kirschstein-NRSA institutional research training grant applications. Applicants are encouraged to confirm the application receipt dates by calling the appropriate IC or checking the NIH-wide program announcement for institutional research training grants at http://grants.nih.gov/training/nrsa.htm.

MODULAR APPLICATIONS AND AWARDS

General

Modular applications and awards employ a simplified process for developing and reviewing application budgets, documenting approved budgets, and making post-award budgetary changes.

Applicability

Modular procedures are required to be used for new, competing continuation, and revised (amended) applications as well as for competing supplements for individual research project grants (R01), small grants (R03), exploratory/development grants (R21), and Academic Research Enhancement Awards (R15) that request up to a total of $250,000 of direct costs per year, regardless of whether the application is an investigator-initiated application or is one submitted in response to a PA/RFA. Modular procedures also apply to SBIR and STTR Phase I grants (R43 and R41) that request up to a total of $100,000 (direct and F&A costs and fee).

Instructions for specific grant mechanisms other than the R01 and guidelines for IC programs may indicate a particular number or range of modules allowed. In addition, an IC may, at its discretion, specify in an RFA that the modular application requirements apply to applications for amounts in excess of the modular ceiling.

Modular applications and awards also are subject to other simplified procedures, specifically just-in-time requirements and SNAP.

Application Requirements

Modular applications are submitted on the PHS 398, with the following modifications.

Budget

Modular applications request direct cost funding in modules of $25,000, up to the ceiling amount (i.e., $250,000 for each year of support under covered mechanisms other than SBIR/STTR Phase I grants and $100,000 for SBIR/STTR Phase I grants) plus applicable F&A costs. The modules should be a reasonable estimate of allowable, allocable, and reasonable costs for the proposed project, since only limited budget information is required for submission of a modular application, the standard application budget forms are not used. Applicants must submit budget information in accordance with the Modular Budget Format Page included in the PHS 398 application instructions. Sample modular application budget pages are available at http://grants.nih.gov/grants/funding/modular/modular.htm.

The modular budget is accompanied by a narrative for all personnel by position, role, and percent level of effort. This includes consultants and any "to be appointed" positions. No individual salary information should be provided. Applicants must use the current salary cap when determining the number of modules (see "Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages"). Given the ability to rebudget and to carry forward unobligated balances, funds generally should be available to cover any modest increase in the statutorily imposed salary cap.

As appropriate, the narrative also 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 percent of effort of key personnel 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 specified 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.

Checklist

The application checklist must be completed and submitted with the application. The checklist should include F&A costs calculated at the current negotiated rate, less exclusions, for the initial budget period and all future budget periods covered by the application.

Non-Compliant Applications

The modular application instructions require only limited budgetary information. Therefore, applications not complying with those instructions will not be accepted for review and will be returned to the applicant by CSR as non-compliant applications.

An application will be considered non-compliant if one or more of the following occurs:

- The direct cost budget is not in modules of $25,000 for each year of support requested.
- A detailed itemized categorical budget is provided.
- The budget narrative justification includes an itemized justification for one or more of the following: equipment, travel, supplies, other expenses, etc., but the number of modules requested for each year is the same, or the information is not intended to explain the request for a different number of modules for one or more years.

A returned application, if revised and resubmitted to NIH in a timely manner, may remain in the review cycle for which it was originally submitted.

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 from the applicant information about “Other Support” and, as applicable, human subjects, animal subjects,

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. In unusual situations, an IC may have to reduce the funding 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.

Post-Award Administration

In accordance with the applicable cost principles and other cost policies included in Subpart A of this part, grantees are required to allocate and account for costs related to their awards by category within their organizational accounting system.

Modular awards are subject to expanded authorities and SNAP.

Grantees may request administrative supplements as under nonmodular awards.

SUPPORT OF SCIENTIFIC MEETINGS (CONFERENCE GRANTS)

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 is required before submission of an application for conference support. Therefore, potential applicants must contact the funding IC 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. NIH will not make an award unless it can be issued before the conference's start date.

Applicability

This section applies to grants that support domestic and international conferences. If a policy is not addressed in this section, the Subpart A coverage applies.

Questions concerning the allowability of conference activity under research grants should be directed to the GMO.

Definitions

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 any country, including the United States.

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).

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 can 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.

Application Requirements

The PHS 398 is to be completed by an organization seeking NIH conference support. Supplemental application instructions for conference grants are available at the Kiosk for Conference Grants at http://grants.nih.gov/grants/funding/r13/index.htm.

Public Policy Requirements and Objectives

In addition to any applicable public policy requirements and objectives specified in Subpart A, conference grant applicants must comply with the *Guidelines on the Inclusion of Women, Minorities, and Persons with Disabilities in NIH Supported Conference Grants* (available through the NIH website at http://grants.nih.gov/grants/policy/policy.htm. Appropriate representation of women, individuals who are members of racial/ethnic minority groups, people with disabilities, and other individuals who have been traditionally underrepresented in science must be included in all aspects of planning, organization, and implementation of NIH-sponsored or -supported meetings. "Appropriate representation" is based on the availability of scientists from these groups known to be working in a particular field of biomedical or behavioral research. If appropriate representation is not apparent, NIH will not make an award until the applicant has submitted acceptable documentation of its compliance.

Application Review

Applications for conference grants will be reviewed for programmatic relevance and for merit as described in the conference grant PA (http://www.niehs.nih.gov/dert/programs/conferen.htm).

Depending on IC policy, applications for conference grants also may be reviewed by the IC's National Advisory Council or Board.

Funding

Grants or cooperative agreements may be used to provide conference support. A cooperative agreement may be awarded if the NIH awarding office 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 office prior approval.

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.

Allowable Costs

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 (or on Behalf of) Federal Employees under Grants."

Meals. When certain meals are an integral and necessary part of a conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, as qualified under "Travel" in this subsection.

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 be used for registration fees paid by the grantee to other organizations on behalf of attendees, provided such fees cover only those allowable costs properly chargeable to the grant.

Salaries. In accordance with the policy of the grantee 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 grantee organization are governed by the grantee'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").

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" in this subsection.

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" in this subsection, 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.

Administrative Requirements

Intellectual Property: Publications, Copyright, and Public Disclosure

If the grantee publishes material developed in whole or in part with NIH funds, the material may be distributed free of charge. If the grantee organization charges for the material, the sales proceeds are considered program income, and must be accounted for as specified in the NGA and reported on the FSR (see "Reporting and Record Retention" in this subsection).

Unless otherwise provided in the terms and conditions of the award, the grantee 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 grantee is cautioned to remind conference participants that any presentation or discussion constitutes public disclosure of information. Any such public disclosure would create a bar and seriously impact the degree to which any intellectual property rights could be protected.

Reporting and Record Retention

Grantees are responsible for submitting the following reports to the NIH awarding office upon completion or termination of a grant in support of a conference.

Progress/Final Report

For single conferences, a final report of the conference must be submitted to the NIH awarding office within 90 days after the end of the project period. The report must include the following:

- Grant number
- Title, date, and place of the conference
- Name of the person shown on the application as the conference director, PI, or PD
- 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.

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 90 days after the end of the project period.

With the approval of the NIH awarding office, 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.

Financial Status Report

An FSR is required from the grantee within 90 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 45 CFR 74.53 or 92.42 (see "Administrative Requirements—Monitoring—Record Retention and Access").

CONSORTIUM AGREEMENTS

General

This section includes the requirements for an applicant/grantee under consortium agreements in which the grantee collaborates with one or more other organizations in carrying out the grant-supported research. The grantee, 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, and all other obligations of the grantee, as specified in the NIHGPS. In general, the requirements that apply to the grantee, including the intellectual property requirements in Subpart A and the program income requirements of the award, also apply to consortium participant(s). Exceptions are noted in this section. The grantee is responsible for including the applicable requirements of the NIHGPS in its agreements with collaborating organizations (see "Written Agreement" in this section).

Under grants that include consortium agreements:

- The award will be made to a single grantee with a single PI, even though one or more organizations other than the grantee will carry out portions of the planned programmatic activity.

- The grantee 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.

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 grantee 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"). Applicants for STTR grants should follow the specific requirements for research collaboration established for that program (see "Grants to For-Profit Organizations").

The following information must be provided to NIH as part of a competing application that proposes consortium arrangements:

- A list of all proposed performance sites, including those of the applicant organization and the consortium participant(s); and
- Complete application budget pages (for the first year and each future year of support requested) for each consortium participant, unless the application is for a modular award (see "Modular Applications and Awards").

The signature of the AOO 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 special condition(s) on the award.

Administrative and Other Requirements

The following highlights several areas within the consortium relationship that the grantee needs to address with the consortium participant to ensure compliance with NIH requirements. The requirement for a written agreement addressing these and other areas is specified in this section.

Public Policy Requirements and Objectives

The grantee 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 and Objectives" for the full statement of these requirements and their applicability to consortium participants.

The grantee 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, 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"). The list of organizations with approved assurances is available at the OHRP website: http://www.hhs.gov/ohrp/ .

The grantee also must ensure that all sites engaged in research involving the use of live, vertebrate animals have an appropriate animal welfare assurance. If collaborating institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional animal welfare program the research will be performed. If an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, an IACUC should be advised about any significant questions or issues raised during a semiannual program inspection of a facility housing a research activity for which that IACUC bears some responsibility or exposure.

Allowable and Unallowable Costs

The grantee must include in consortium agreements the applicable government-wide cost principles and NIH cost policies described in "Cost Considerations" and, as appropriate, requirements related to allowable and unallowable costs in other sections of Subpart B. For example, a university grantee must flow down the cost principles of OMB Circular A-122 to a consortium participant that is a non-profit research organization. This includes the application of F&A rates in determining consortium budgets and the reimbursement of costs.

Approval Authorities

The grantee is responsible for obtaining NIH awarding office approval for any actions to be undertaken by consortium participants that require prior approval. Grantees may establish requirements for review of consortium participants' activities consistent with those requirements and with any authorities provided to the grantee; however, a grantee may not provide any authority to a consortium participant that the grantee has not been provided under its NIH award.

Regardless of whether there is a change in scope, in all cases, if a grantee (or consortium participant) proposes the transfer of work to a foreign site, awarding office prior approval is required.

Tangible Personal Property

Exempt Property

If the grantee provides exempt property to a consortium participant or authorizes a consortium participant to purchase property that would be considered exempt if acquired by the grantee, the grantee may vest title in the consortium participant upon transfer or purchase or may reserve the right to do so at a later time. The grantee 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").

Nonexempt Property

If the grantee provides nonexempt property to a consortium participant or authorizes a consortium participant to purchase property that would be considered nonexempt if purchased by the grantee, title to such property must remain with the grantee or be vested in the grantee upon acquisition of the property. The grantee may establish use, accountability, and disposition

requirements for the property, provided they are consistent with, and do not impair, the grantee's ability to comply with the requirements of 45 CFR Part 74 or 45 CFR Part 92, as appropriate.

Audit

The grantee must require consortium participants to comply with the requirements of OMB Circular A-133 or 45 CFR 74.26(d), as applicable, for audit of NIH grant funds expended by consortium participants. A consortium participant also may be a direct NIH grantee or contractor or may be receiving funds only under the consortium agreement. Regardless, if a non-profit consortium participant meets the OMB Circular A-133 threshold criterion of aggregate annual expenditures of $500,000 or more under applicable Federal awards, the grantee must receive a copy of that organization's A-133 audit and take appropriate action based on any findings that relate to the consortium agreement. If a consortium participant will not reach that expenditure threshold, the grantee is responsible for monitoring the organization's activities to ensure compliance with NIH requirements. The grantee may not require a consortium participant to have an audit and charge the audit costs to NIH grant funds unless required or authorized by OMB Circular A-133 or 45 CFR 74.26(d).

Written Agreement

The grantee must enter into a formal written agreement with each consortium participant that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate a smoothly functioning collaborative venture. At a minimum, this agreement must include the following:

- Identification of the PI and individuals responsible for the research activity at each consortium participant along with their roles and responsibilities
- 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, and procedures for review and approval of expenditures of grant funds at each organization
- If different from those of the grantee, 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)
- 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 and Objectives")
- Whether the financial conflict of interest requirements of the collaborating organization or those of the grantee apply

- A provision addressing ownership and disposition of data produced under the consortium agreement

- A provision making the NIH data sharing and inventions and patent policy, including a requirement to report inventions to the grantee (see "Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources"), 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 grantee can fulfill its responsibilities to NIH

- Provisions regarding property (other than intellectual property), program income, publications, reporting, and audit necessary for the grantee to fulfill its obligations to NIH.

GRANTS TO FOREIGN INSTITUTIONS, INTERNATIONAL ORGANIZATIONS, AND DOMESTIC GRANTS WITH FOREIGN COMPONENTS

General

Most of the policies contained in Subpart A of this part apply to NIH grants made to foreign institutions and international organizations (hereafter "foreign grants"), including the requirements of 45 CFR Part 74 or 45 CFR Part 92 and the cost principles incorporated by reference in those regulations. If an applicant/grantee would be unable to comply with these requirements, the AOO should contact the GMO. Specific exceptions and modifications of Subpart A requirements for foreign grants, and highlights of other policies, are set forth in this section. This section also includes policies that apply to domestic grants with a foreign component.

Eligibility

In general, foreign institutions and international organizations, including public or private non-profit or for-profit organizations, are eligible to apply for research project grants. Foreign institutions 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 mechanisms, 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 grantee or by a researcher employed by a foreign institution, whether or not grant funds are expended. Activities that would meet this definition include the following:

- The involvement of human subjects or animals

- Extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities

- Any activity of the grantee that may involve the population, environment, resources, or affairs of a foreign country.

Foreign travel exclusively for consultation is not considered a "foreign component."

See "Support of Scientific Meetings (Conference Grants)" in this subpart 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 an American citizen or a non-citizen national to study in a foreign institution. (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.)

Application Review

Applications from foreign institutions 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.

Research grant applications from foreign or international organizations may not be funded unless approved by the IC National Advisory Council or Board.

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 and Objectives" in Subpart A of this part. Several of the public policy requirements and objectives are highlighted below:

- *Research misconduct.* The research misconduct requirements included in "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Research Misconduct" apply to foreign grants.

- *Animal welfare.* The animal welfare requirements contained in "Public Policy Requirements and Objectives—Animal Welfare" apply to foreign grants.

- *Human subjects.* The human subjects requirements contained in "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects,"

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.

- *Inclusiveness in research design.* Foreign grants are subject to the requirements for inclusion of women, members of minority groups, and children in research design as specified in "Public Policy Requirements and Objectives—Requirements for Inclusiveness in Research Design."

- *Civil rights.* None of the civil rights requirements specified in "Public Policy Requirements and Objectives—Civil Rights" apply to foreign grants.

- *Lobbying.* The requirements of "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying," 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 and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Nondelinquency on Federal Debt."

- *Debarment and suspension.* Applicants/grantees 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 45 CFR Part 76. All other foreign institutions and international organizations are subject to these requirements.

- *Drug-free workplace.* Foreign applicants and grantees may be exempted from the drug-free workplace requirements of 45 CFR Part 76 based on a documented finding by the NIH awarding office that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government.

Funding and Payment

The application budget, requests for funds, and financial reports (see "Reporting and Record Retention" in this section) must be stated in U.S. dollars. Once an award is made, NIH will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

Awards to foreign institutions and international organizations are not paid through PMS. These grants normally will be paid by U.S. Treasury check by OFM, NIH on a predetermined quarterly advance basis, usually in four equal installments. If the amount advanced to an organization based on the predetermined quarterly advance is insufficient to meet the grant's cash requirements, the grantee must make a written request to the GMO for any additional funds needed. All payments will be in U.S. dollars. Foreign grantees are strongly encouraged to use U.S. banks to ensure that payments arrive on time. The funding and payment information outlined in this subsection applies when the foreign institution is the grantee organization. When a foreign component participates in a consortium arrangement, the funding and payment information should be reflected in the formal written agreement.

Any questions regarding payments to foreign grantees may be addressed to OFM (see Part III for address and telephone and fax numbers).

Allowable and Unallowable Costs

The costs that are generally allowable under grants to domestic organizations also are allowable under foreign grants, with the following exceptions:

- *A&R.* Unallowable under foreign grants and domestic grants with foreign components.
- *Customs and import duties.* Unallowable under foreign grants and domestic grants with foreign components. This includes consular fees, customs surtax, value-added taxes, and other related charges.
- *F&A costs.* With the exception of American University of Beirut and the World Health Organization, full F&A costs will not be allowed. However, NIH provides limited F&A costs (8 percent of total direct costs less equipment) to foreign institutions and international organizations to support the costs of compliance with NIH requirements including, but not limited to, protection of human subjects, animal welfare, and research misconduct. NIH will not support the acquisition of, or provide for depreciation on, any capital expenditures, or support the normal, general operations of foreign and international organizations.

Administrative Requirements

Changes in Project and Budget

Foreign grants are included in expanded authorities. Inclusion in SNAP is at the discretion of the NIH awarding office and will be specified on the NGA.

Change in Scope

A change in the performance site within a foreign country or performance in a country other than that specified in the approved application requires NIH awarding office prior approval. The transfer of work by a domestic grantee to a foreign component also requires awarding office prior approval.

Change of Grantee Organization

A change of grantee organization that involves the transfer of a grant to or between foreign institutions or international organizations requires approval of the NIH awarding office and it's National Advisory Council or Board. NIH awarding office approval also is required for the transfer of a grant from a foreign organization to a domestic organization.

Audit

Foreign grantees are subject to the same audit requirements as for-profit organizations (specified in 45 CFR 74.26(d) and in "Grants to For-Profit Organizations" in this subpart).

Reporting and Record Retention

Foreign grantees must submit annual FSRs in U.S. dollars, whether or not they are under SNAP. This is due to the fact that foreign grantees are not paid through PMS and, therefore, do not submit the SF 272 (which NIH uses in lieu of the annual FSR for domestic awards under SNAP). The currency rate in effect at the time the FSR is prepared should be used in preparing the report.

Record retention requirements are the same as those for domestic grantees.

GRANTS TO FEDERAL INSTITUTIONS AND PAYMENTS TO (OR ON BEHALF OF) FEDERAL EMPLOYEES UNDER GRANTS

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 Subpart A due to the recipient's status as a Federal institution. This section specifies those differences as well as differences in treatment among different Federal institutions. In addition, this section 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.

Eligibility

In general, Federal institutions are eligible to apply for NIH grants, including research project grants and training grants. 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 grantee 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 AOO'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.

VA-University Affiliations

Investigators with joint appointments at a VAMC (VA hospital) and an affiliated university must have an MOU that specifies the title of the investigator's appointment, the responsibilities (at both the university and the VAMC) of the proposed investigator, and the percentage of effort available for research. The MOU must be signed by the appropriate officials of the grantee 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 his or her 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 AOO 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 section).

Payment

NIH grants to DoD normally will be paid by U.S. Treasury check after submission of the appropriate interagency form to OFM, NIH. Payments to all other Federal departments and agencies generally will be accomplished by transfers of funds between appropriations.

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 for State, local, and Indian tribal governments (OMB Circular A-87) will apply.

Salaries. See "Federal (U.S. Government) Employees" in this subsection.

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, an outpatient, or a study subject, special 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 73, Subpart J for additional guidance.)

Only four types of costs—consultant fees, outpatient or subject costs, salary or fringe benefits, and travel costs—can be charged to NIH grants on behalf of Federal employees, whether by a grantee or a consortium participant, and under the conditions specified only. Applicants/grantees should advise any Federal employees with whom these types of arrangements may be made to consult with their employing agency concerning their ability to meet the required conditions. 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 he or she is authorized to work on the grant-supported activity during non-duty hours or while on authorized leave, and can be paid for his or her efforts.

Outpatient or subject costs. These costs are allowable when the employee is an outpatient or subject under study in connection with grant-supported activities.

Salary or fringe benefits. Under grants to VANPCs, in accordance with the established policies and salary structure of the VANPC, if the PI is a part-time VA employee, NIH grant funds may be 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. Therefore, if the 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. An NIH grant may not be the source of funding for an increase in an investigator's salary regardless of the type of entity with which the investigator holds an appointment (e.g., university, VA, or VANPC).

Salary payments may be made from NIH grant funds to career, career-conditional, or other Federal employees (civilian or uniformed services) with permanent appointments provided under existing position ceilings of a Federal component only if prior approval is obtained from an authorized official of the employee's agency and the employee is one of the following:

- 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

  - grantee has obtained written prior approval from the NIH awarding office;

  - 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 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 PI for an NIH grant may not be participating through an IPA. On a case-by-case basis, the NIH awarding office may determine that certain other key personnel on the project are sufficiently critical to its long-term success that participation through an IPA is not appropriate.

  - Before making any payment from NIH grant funds to such an employee, the grantee 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.

Unless the payments meet one the above-described exceptions, no salary or fringe benefit payments may be made from NIH grant funds to support career, career-conditional, or other Federal employees (civilian or uniformed services) with permanent appointments provided for under existing position ceilings of a given Federal component. 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 costs associated with an individual participating in an official capacity as a Federal employee are not allowable costs under an NIH grant.

Payments to temporary employees specifically hired to assist in the performance of an NIH grant are allowable.

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, educational institution, or other non-profit organization.

Such payments must be made in accordance with established organizational policy, 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.

Administrative Requirements

Equipment Accountability

NIH will consider all nonexpendable personal property acquired under a grant awarded to a Federal institution as exempt (see 45 CFR 74.33) for purposes of determining the accountability requirements of 45 CFR 74.34. However, NIH has the right to require transfer of equipment, including title, to NIH or an eligible third party named by the NIH awarding office under the conditions specified in 45 CFR 74.34.

Procurement Requirements

Procurement under grants to Federal institutions is governed by the FAR and the recipient agency's FAR supplement.

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 licensing requirements of 37 CFR Part 401. (See https://s-edison.info.nih.gov/iEdison/ for reporting requirements.) 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.

Reporting Requirements

Federal institutions must submit annual FSRs regardless of whether the award is subject to SNAP. This is due to the fact that these grants are paid by OFM, NIH rather than through PMS.

GRANTS TO FOR-PROFIT ORGANIZATIONS

General

Some of the terms and conditions for grants to for-profit (commercial) organizations vary from the standard terms and conditions included in Subpart A of this part. In addition, the terms and conditions of the SBIR and STTR programs vary from those otherwise applicable to for-profit organizations. This section 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 Subpart A that apply equally to for-profit and non-profit recipients. If an exception is not stated below or in the NGA, the terms and conditions specified in Subpart A apply, including requirements for the protection of human subjects and animal welfare.

Eligibility

For-profit organizations are eligible to apply under all NIH programs and support mechanisms unless specifically excluded by statute.

Allowable and Unallowable Costs

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 (available on-line at http://www.gsa.gov). The cost principles in 45 CFR Part 74, Appendix E, are used to determine allowable costs under NIH grants to proprietary hospitals.

Independent Research and Development Costs

As provided in 45 CFR 74.27(a), NIH does not allow for-profit organizations to be reimbursed for IR&D (self-sponsored) costs.

Facilities and Administrative Costs (Indirect Costs)

F&A costs are allowable under awards to for-profit organizations.

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 grantee 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 grantee.

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.

Intellectual Property

Intellectual property requirements set forth in 37 CFR Part 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 grantee is a for-profit organization, assignment of invention rights to a third party does not require NIH approval. (See "Administrative Requirements—Availability of Research Results: Publications,

Intellectual Property Rights, and Sharing Research Resources.”). Additional information about the requirements of 37 CFR 401 may be obtained from the Extramural Inventions and Technology Resources Branch, OPERA, NIH (see Part III for address and telephone number).

To the extent authorized by 35 U.S.C. 205 (the Patent Act, as amended), the Federal government will not make public any information disclosing a Federal government-supported invention.

Program Income

Consistent with expanded authorities, for-profit grantees, 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.”

Operating Authorities

Awards to for-profit organizations generally are subject to expanded authorities; however, some mechanisms do not allow automatic carryover of unobligated balances of funds. Under those mechanisms, the NIH awarding office will specify the disposition of the reported unobligated balance in the NGA. (See “Administrative Requirements—Changes in Project and Budget”).

Audit

The requirements for non-Federal audits of for-profit organizations are specified in 45 CFR 74.26(d). A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $500,000 or more under one or more HHS awards (as a direct grantee and/or under a consortium participant) and at least one of those awards is an HHS grant. 45 CFR 74.26(d) incorporates the thresholds and deadlines of OMB Circular A-133 but provides for-profit organizations two options regarding the type of audit that will satisfy the audit requirements. The grantee either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the “Yellow Book”), GPO stock 020-000-00-265-4, of all the HHS awards, or (2) an audit that meets the requirements of OMB Circular A-133.

OMB Circular A-133 is available electronically at http://www.whitehouse.gov/omb/circulars/a133/a133.html.

The Government Auditing Standards are available electronically at http://www.gao.gov/govaud/ybk01.htm. Audits must be completed and submitted to the following office 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:

National External Audit Review Center
HHS Office of Audit Services
323 West 8th Street
Lucas Place
Room 514
Kansas City, MO 64105

For-profit organizations expending less than $500,000 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.

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.

Both the SBIR and STTR programs consist of the following three phases; however, individual projects may not be eligible for all three phases:

- *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. Only Phase I grantees are eligible to receive Phase II funding. Unless submitted as a Fast-Track application (see below), Phase II applications may be submitted only after the Phase I award is made. 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 expiration date of the Phase I award.

- *Phase III.* The objective of this phase, where appropriate, is for the SBC to pursue, with non-Federal funds, the commercialization of the results of the research or R&D funded in Phases I and II.

There are two major differences between the SBIR and STTR programs:

- The STTR program requires that the SBC formally partner with a single, non-profit research institution in the collaborative conduct of a project that has potential for commercialization. To be eligible for an STTR award, at least 40 percent of the research must be performed by the SBC and at least 30 percent of the research must be performed by a domestic non-profit 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. (The same requirement applies to Phase I and to Phase II.) STTR grants are awarded to the SBC, which will receive all of the funding for the project and disperse the appropriate funding to the research institution. The SBIR program does not have this requirement; therefore, the SBC may conduct the entire SBIR project without outside collaboration.

- The SBIR program requires that the primary employment of the PI (greater than 50 percent of the individual's time) be with the SBC at the time of award and during the conduct of the project. The STTR program does not have this requirement, i.e., the PI may have his or her primary employment with an organization other than the SBC, including the collaborating research institution. However, there must be an official relationship between the PI and the SBC. As an eligibility criterion, NIH also requires the PI to devote at least 10 percent of his or her time to the STTR project.

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. Typically, Fast-Track applications will receive a single rating. NIH determines whether to allow SBCs to use the Fast-Track review option. Therefore, before submitting applications for Fast-Track review, applicants are strongly encouraged to consult with cognizant NIH program staff. SBIR/STTR Phase I and Phase II applications submitted concurrently without prior consultation with NIH may be redirected for review under NIH's normal review procedures. For additional information on the submission of Fast-Track applications, see the SBIR/STTR program solicitations and instructions at http://grants.nih.gov/grants/funding/sbir.htm.

Eligibility

Qualification as a Small Business Concern

Each organization receiving a grant under the SBIR/STTR programs must qualify as a U.S.-owned SBC—an entity that, at the time of the Phase I and Phase II awards, meets all of the following criteria:

- The entity is 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 U.S. economy through payment of taxes or use of American products, materials or labor.

- It is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust, or cooperative. If the entity is a joint venture, there can be no more than 49 percent participation by foreign business entities.

- As provided by the express terms of 13 CFR 121.702(a), it is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. In the case of a joint venture, each party to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. Under these regulations, corporations or artificial entities cannot quality as individuals who are U.S. citizens. Further, indirect ownership of the entity by a U.S. citizen does not satisfy the requirements of 13 CFR 121.702(a).

- *Example 1.* An entity applying for an SBIR/STTR grant is 100 percent owned by Company A. Company A is 100 percent owned by U.S. citizens. The entity is not eligible for support under the SBIR/STTR program because it is not 51 percent directly owned and controlled by citizens of, or permanent resident aliens in, the United States.

- *Example 2.* An entity applying for an SBIR/STTR grant is 51 percent owned by U.S. citizens of and permanent resident aliens in the United States and 49 percent owned by a corporation. The entity is eligible for support under the SBIR/STTR program, assuming it meets the other eligibility criteria (e.g., size), because 51 percent of the ownership rests directly with U.S. citizens and permanent resident aliens of the United States.

- The entity, including its affiliates, cannot have more than 500 employees. In accordance with 13 CFR Part 121.103, affiliation exists when, either directly or indirectly, (1) one concern controls or has the power to control the other, or (2) a third party or parties controls or has the power to control both. One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space, employees, and/or other facilities (e.g., laboratory space). The research and analytical work performed by the grantee organization under an SBIR/STTR award is to be conducted in research space occupied by, available to, and under the control of, the grantee. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR grantee has entered into a consortium arrangement with another organization for a specific, limited portion of the research project. See 13 CFR 121.3-2(a) and 13 CFR 121.3-2(t) for additional information concerning this criterion.

All appropriate factors will be considered in determining whether an entity qualifies as an SBC, including common ownership, common management, and contractual relationships.

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), the investigator must thoroughly justify in the application the need for use of a foreign site. Similarly, in those rare instances where it may be necessary to purchase materials from other countries, investigators must thoroughly justify the request. NIH will consider these instances on a case-by-case basis, and they should be discussed with cognizant NIH staff before submitting an application. Whether the request is approved or disapproved, it will be explicitly addressed in the NGA 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 grants.

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. In addition, 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.

For STTR awards (both Phase I and Phase II), at least 40 percent of the work is to be performed by the SBC and at least 30 percent of the work is to be performed by the single, non-profit research institution. The basis for determining the percentage of work to be performed by each of the cooperating parties is the total of direct and F&A costs attributable to each party, unless otherwise described and justified in the "Contractual Arrangements" portion of the "Research Plan" section of the grant application.

Public Policy Requirements and Objectives

The requirements concerning disclosure of financial conflicts of interest (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Financial Conflict of Interest") do not apply to applications or awards under Phase I of the SBIR/STTR programs.

Allowable Costs and Fee

Profit or Fee

A reasonable profit or fee may be paid to a SBC receiving an award under Phase I or Phase II of the SBIR and STTR programs. 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.

Facilities and Administrative Costs (Indirect Costs)

Phase I

If the applicant SBC has a currently effective indirect cost rate(s)[18] 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 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.

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 25 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 25 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 25 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 website or by telephone (see Part III of the NIHGPS).

Administrative Requirements

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. 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.

[18] 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."

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.

Intellectual Property

Rights to data, including software developed under the terms of any funding agreement resulting from an NIH award, shall remain with the grantee 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 grantee's permission for a period of 4 years from completion of the project under which the data were generated.

The STTR program requires that the small business grantee 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. (A model agreement, entitled "Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization," is available at the NIH website at http://grants.nih.gov/grants/funding/sbir.htm.) By signing the face page of the grant application, the SBC's AOO certifies that the agreement with the research institution will be effective at the time the grant award is made. A copy of the agreement must be furnished upon request to the NIH awarding office.

SBIR/STTR grantees are covered by 37 CFR 401 with respect to inventions and patents (see "Grants to For-Profit Organizations—Administrative Requirements—Intellectual Property" in this section).

Data Sharing

Applicants for SBIR Phase II funding of $500,000 or more of direct costs in any single year must comply with the NIH policy on data sharing 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 subsection, whether or not the award meets the threshold for data sharing, NIH will not release data outside the Federal government without the grantee's permission for a period of 4 years from completion of the project under which the data were generated. The entire policy may be found at http://grants.nih.gov/grants/policy/data_sharing.

RESEARCH PATIENT CARE COSTS

General

This section 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 45 CFR Part 74, Appendix E, Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals. In addition, specific NIH programs may have additional or alternative requirements with which an applicant/grantee must comply. This includes the GCRC guidelines as specified in this section.

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 in an affiliated medical school/university based on an organizational fee schedule, or (3) 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 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 heath 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.

Policy

NIH provides funds for research patient care costs under grants. Research patients may receive routine services as inpatients or ancillary services as either inpatient or outpatient subjects/volunteers. 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 DCA office. These rates must be shown in all requests and/or claims for reimbursement of research patient care costs. Hospital grantees that expect to incur $100,000 or less in research patient care costs per budget period on a single NIH grant and consortium participants/contractors under grants 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 DCA when required may result in the disallowance of all research patient care costs charged to a grant.

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 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 grantee 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.

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 grantee's records. These individuals may include the following:

- People 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; and sick people brought to the hospital solely for studies when they otherwise would not require hospitalization.

- Sick people of research importance to the investigator but without funds of their own 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.

- Sick people with limited personal funds or health insurance but who are not willing 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. Ordinarily, NIH expects the patient and/or third party to pay the total costs of the usual care portions of the hospitalization. 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.

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 office is obligated to reimburse the grantee for such costs. Provisional rates must be adjusted if a lower final rate is negotiated.

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 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.

Special Procedures for Certain Hospitals

Grantees

If a grantee does not meet the threshold for negotiation of a research patient care rate agreement with DCA in a given budget period, as specified under "Policy" in this section, 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 grantee expects to incur. In all other cases, the grantee 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.

Consortium Participants/Contractors under Grants

If a hospital incurring research patient care costs is not the grantee, the grantee 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 DCA.

If a participating hospital expects to incur more than $100,000 in research patient care costs as specified under "Policy" in this section, the grantee must negotiate a rate for that hospital unless the relationship between the grantee and the hospital is considered "less-than-arms-length." In this case, the grantee should contact the GMO to determine whether DCA 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 section), the grantee 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 grantee will apply the thresholds to each hospital individually.

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 grantee 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 grantee determines that the balance of the patient's bill may be charged to the grant (see "Allowable Costs" in this section), 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.

Program Requirements

An individual NIH IC/program may adopt special implementing procedures consistent with this section to meet its own specific needs. As an example, the majority of NIH-supported discrete centers are funded by NCRR's GCRC program, which has developed detailed guidelines for the operation of these centers (see Part III for NCRR contact information).

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 NGA.

Institutes and Centers

John E. Fogarty International Center (FIC) http://www.fic.nih.gov/	
Chief Grants Management Officer Building 31C, Room B2C29, MSC-2220 Bethesda, MD 20892-2220 301/451-6830 301/594-1211 (fax)	Extramural Program Official Building 31C, Room B2C29, MSC-2220 Bethesda, MD 20892-2220 301/496-1415 301/402-2173 (fax)
National Cancer Institute (NCI) **http://www.nci.nih.gov**	
Chief Grants Management Officer 6120 Executive Boulevard Executive Plaza South, Room 234, MSC-7150 Bethesda, MD 20892-7150 301/496-7753 301/402-3409 (fax)	Extramural Program Official 6116 Executive Boulevard Executive Plaza North, Suite 8001, MSC-7405 Bethesda, MD 20892-7405 301/496-5147 301/402-0956 (fax)
National Center for Complementary and Alternative Medicine (NCCAM) **http://nccam.nih.gov**	
Chief Grants Management Officer 6707 Democracy Boulevard, II Suite 401, MSC-5475 Bethesda, MD 20892-5475 301/451-6330 301/480-1552 (fax)	Extramural Program Official 6707 Democracy Boulevard, II Suite 401, MSC-5475 Bethesda, MD 20892-5475 301/496-1944 301/480-3621 (fax)
National Center for Research Resources (NCRR) **http://www.ncrr.nih.gov**	
Chief Grants Management Officer 6701 Democracy Boulevard One Democracy Plaza, Suite 1038, MSC-4874 Bethesda, MD 20892-4874 301/435-0844 301/480-3777 (fax)	Extramural Program Official Building 31, Room 3B11, MSC-2128 Bethesda, MD 20892-2128 301/496-6023 301/480-3658 (fax)
National Center on Minority Health and Health Disparities (NCMHD) **http://www.ncmhd.nih.gov**	
Chief Grants Management Officer 6707 Democracy Boulevard, Suite 800, MSC 5465 Bethesda, MD 301/402-1366 301/402-4049	Extramural Program Official 6707 Democracy Boulevard, Suite 800, MSC 5465 Bethesda, MD 301/402-1366 301/402-4049

National Eye Institute (NEI) http://www.nei.nih.gov	
Chief Grants Management Officer 6120 Executive Boulevard Executive Plaza South, Room 350, MSC-7164 Bethesda, MD 20892-7164 301/451-2020 301/496-9997 (fax)	Extramural Program Official 6120 Executive Boulevard Executive Plaza South, Room 350, MSC-7164 Bethesda, MD 20892-7164 301/496-5301 301/402-0528 (fax)
National Heart, Lung and Blood Institute (NHLBI) http://www.nhlbi.nih.gov	
Chief Grants Management Officer 6701 Rockledge Drive Rockledge II, Room 7160, MSC-7926 Bethesda, MD 20892-7926 301/435-0144 301/480-3310 (fax)	Extramural Program Official 6701 Rockledge Drive Rockledge II, Room 7100, MSC-7922 Bethesda, MD 20892-7922 301/435-0260 301/480-3460 (fax)
National Human Genome Research Institute (NHGRI) http://www.nhgri.nih.gov or http://www.genome.gov	
Chief Grants Management Officer Building 31, Room B2B34, MSC-2031 Bethesda, MD 20892-2031 301/496-7858 301/402-1951 (fax)	Extramural Program Official Building 31, Room B2B07, MSC-2033 Bethesda, MD 20892-2033 301/435-5536 301/480-2770 (fax)
National Institute on Aging (NIA) http://www.nia.nih.gov	
Chief Grants Management Officer 7201 Wisconsin Avenue Gateway Bldg., Room 2N212, MSC-9205 Bethesda, MD 20892-9205 301/496-1472 302/402-3672 (fax)	Extramural Program Official 7201 Wisconsin Avenue Gateway Bldg., Room 2C218F, MSC-9205 Bethesda, MD 20892-9205 301/496-9322 301/402-2945 (fax)
National Institute on Alcohol Abuse and Alcoholism (NIAAA) http://www.niaaa.nih.gov	
Chief Grants Management Officer 6000 Executive Boulevard Willco Building, Suite 504, MSC-7003 Bethesda, MD 20892-7003 301/443-4704 301/443-3891 (fax)	Extramural Program Official 6000 Executive Boulevard Willco Building, Suite 409, MSC-7003 Bethesda, MD 20892-7033 301/443-5494 301/443-6077 (fax)
National Institute of Allergy and Infectious Diseases (NIAID) http://www.niaid.nih.gov	
Chief Grants Management Officer 6700-B Rockledge Drive, Room 2116, MSC-7614 Bethesda, MD 20892-7614 301/496-7075 301/480-3780 (fax)	Extramural Program Official 6700-B Rockledge Drive, Room 2141, MSC-7610 Bethesda, MD 20892-7610 301/496-7291 301/402-0369 (fax)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) http://www.niams.nih.gov	
Chief Grants Management Officer 6701 Democracy Boulevard One Democracy Plaza, Suite 800, MSC-4872 Bethesda, MD 20892-4872 301/594-3535 310/480-5450 (fax)	Extramural Program Official 6701 Democracy Boulevard One Democracy Plaza, Suite 800, MSC-4872 Bethesda, MD 20892-4872 301/594-2463 301/480-4543 (fax)
National Institute of Biomedical Imaging and Bioengineering (NIBIB) **http://www.nibib.nih.gov**	
Chief Grants Management Officer 6707 Democracy Boulevard, Suite 900, MSC-5489 Bethesda, MD 20892-5489 301/451-4782 301/408-4974	Extramural Program Official 6707 Democracy Boulevard, Suite 200, MSC-5489 Bethesda, MD 20892-5489 301/451-4772 301/451-4973
National Institute of Child Health and Human Development (NICHD) **http://www.nichd.nih.gov**	
Chief Grants Management Office 6100 Executive Boulevard, Room 8A01A MSC-7510 Bethesda, MD 20892-7510 301/496-5001 301/480-4782 (fax)	Extramural Program Official 6100 Executive Boulevard, Room 6154, MSC-7510 Bethesda, MD 20892-7510 301/435-6856 301/402-2083 (fax)
National Institute on Deafness and Other Communication Disorders (NIDCD) **http://www.nidcd.nih.gov**	
Chief Grants Management Officer 6120 Executive Boulevard Executive Plaza South, Suite 400C, MSC-7180 Bethesda, MD 20892-7180 301/402-0909 301/402-1758 (fax)	Extramural Program Official 6120 Executive Boulevard Executive Plaza South, Suite 400C, MSC-7180 Bethesda, MD 20892-7180 301/496-8693 301/402-6250 (fax)
National Institute of Dental and Craniofacial Research (NIDCR) **http://www.nidcr.nih.gov**	
Chief Grants Management Officer 45 Center Drive Natcher Bldg., Room 4AN.44B, MSC-6402 Bethesda, MD 20892-6402 301/594-4808 301/480-3562 (fax)	Extramural Program Official 45 Center Drive Natcher Bldg., Room 4AN.18E, MSC-6402 Bethesda, MD 20892-6402 301/594-4848 301/480-8138 (fax)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) http://www.niddk.nih.gov	
Chief Grants Management Officer 6707 Democracy Boulevard 2 Democracy Plaza, Room 731, MSC-5456 Bethesda, MD 20892-5456 301/594-8854 301/480-3504 (fax)	Extramural Program Official 6707 Democracy Boulevard 2 Democracy Plaza, Room 631, MSC-5456 Bethesda, MD 20892-5456 301/594-8834 301/480-3504 (fax)
National Institute on Drug Abuse (NIDA) **http://www.nida.nih.gov**	
Chief Grants Management Officer 6101 Executive Boulevard Neuroscience Center, Suite 242, MSC-8403 Bethesda, MD 20892-8403 301/443-6710 301/594-6849 (fax)	Extramural Program Official 6101 Executive Boulevard Neuroscience Center, Suite 200, MSC-8401 Bethesda, MD 20892-9547 301/443-8401 301/443-0538 (fax)
National Institute of Environmental Health Sciences (NIEHS) **http://www.niehs.nih.gov**	
Chief Grants Management Officer P.O. Box 12233 Research Triangle Park, NC 27709 919/541-7628 919/541-2860 (fax)	Extramural Program Official P.O. Box 12233 Building 3, Room 301 Research. Triangle Park, NC 27709 919/541-7723 919/541-2843 (fax)
National Institute of General Medical Sciences (NIGMS) **http://www.nigms.nih.gov**	
Chief Grants Management Officer 45 Center Drive Natcher Bldg., Room 2AN.50B, MSC-6200 Bethesda, MD 20892-6200 301/594-5135 301/480-1969 (fax)	Extramural Program Official 45 Center Drive Natcher Bldg., Room 2AN.24G, MSC-6200 Bethesda, MD 20892-6200 301/594-3910 301/480-1852 (fax)
National Institute of Mental Health (NIMH) **http://www.nimh.nih.gov**	
Chief Grants Management Officer 6001 Executive Boulevard Neuroscience Center, Room 6115, MSC 9605 Bethesda, MD 20892-9605 301/443-3066 301/443-6885 (fax)	Extramural Program Official 6001 Executive Boulevard Neuroscience Center, Room 6120 Bethesda, MD 20892-9605 301/443-5047 301/443-9474 (fax)
National Institute of Neurological Disorders and Stroke (NINDS) **http://www.ninds.nih.gov**	
Chief Grants Management Officer 6001 Executive Boulevard Neuroscience Center, Room 3254, MSC-9537 Bethesda, MD 20892-9537 301/496-9231 301/402-0219 (fax)	Extramural Program Official 6001 Executive Boulevard Neuroscience Center, Room 3307, MSC-9537 Bethesda, MD 20892-9537 301/496-9248 301/402-4370 (fax)

National Institute of Nursing Research (NINR) http://www.nih.gov/ninr	
Chief Grants Management Officer 6701 Democracy Boulevard One Democracy Plaza, Suite 710, MSC-4870 Bethesda, MD 20892-4870 301/594-6869 301/402-4502 (fax)	Extramural Program Official 6701 Democracy Boulevard One Democracy Plaza, Suite 710, MSC-4870 Bethesda, MD 20892-4870 301/594-6423 301/480-8260 (fax)
National Library of Medicine (NLM) **http://www.nlm.nih.gov**	
Chief Grants Management Officer 6705 Rockledge Drive Rockledge I, Suite 301, MSC-7968 Bethesda, MD 20892-7968 301/496-4222 301/402-0421 (fax)	Extramural Program Official Building 38A, Room 5N503, MSC-6075 Bethesda, MD 20892-6075 301/496-4621 301/402-0421 (fax)

Other NIH Offices

<table>
<tr><th colspan="2">Office of Extramural Research
Office of Policy for Extramural Research Administration (OPERA)
http://www.nih.gov/grants/oer.htm</th></tr>
<tr><td>Division of Extramural Outreach and Information Resources(DEOIR)
e-mail: GrantsInfo@nih.gov
301/435-0714
301/480-0525 (fax)</td><td>Extramural Inventions and Technology Resources Branch
6705 Rockledge Drive
Rockledge I, MSC-7980
Bethesda, MD 20892-7980
301/435-1986 or 1-866-504-9552
301/480-0272 (fax)</td></tr>
<tr><td>Division of Grants Policy
6705 Rockledge Drive
Rockledge I, MSC-7974
Bethesda, MD 20892-7974
301/435-0949
301/435-3059 (fax)</td><td>Grants Compliance and Oversight Branch
6705 Rockledge Drive
Rockledge I, MSC-7974
Bethesda, MD 20892-7974
301/435-0930
301/435-3059 (fax)</td></tr>
<tr><th colspan="2">Office of Laboratory Animal Welfare (OLAW)
http://grants.nih.gov/grants/olaw/olaw.htm</th></tr>
<tr><td colspan="2">6705 Rockledge Drive
Rockledge I, Suite 360, MSC-7982
Bethesda, MD 20892-7982
301/496-7163</td></tr>
<tr><th colspan="2">Center for Scientific Review (CSR)
http://www.csr.nih.gov</th></tr>
<tr><td colspan="2">Division of Receipt and Referral
6701 Rockledge Drive
Rockledge II, MSC-7768
Bethesda, MD 20892-7768
Referral Office 301/435-0715</td></tr>
<tr><th colspan="2">Office of Biotechnology Activities (OBA)
http://www4.od.nih.gov/oba</th></tr>
<tr><td colspan="2">6705 Rockledge Drive
Suite 750, MSC-7985
Bethesda, MD 20892-7985
301/496-9838</td></tr>
<tr><th colspan="2">Office of Intramural Research (OIR)
http://www1.od.nih.gov/oir/sourcebook/oir/oir-staff.htm#OIR</th></tr>
<tr><td colspan="2">6011 Executive Boulevard, Suite 325
Rockville, MD 20852
301/496-7057
301/402-3257 (fax)</td></tr>
</table>

Office of Financial Management (OFM) **http://www4.od.nih.gov/ofm**	
To register for electronic submission of Financial Status Reports: Government Accounting Branch 301/402-5297 or access website: http://commons.era.nih.gov/commons/	Hard-copy submission of Financial Status Reports: Building 31, Room B1B05 MSC-2050 Bethesda, MD 20892-2050 301/402-5297
Office of Acquisition Management and Policy (OAMP) **Division of Financial Advisory Services (DFAS)** **http://oamp.od.nih.gov/dfas/dfas.htm**	
6100 Executive Boulevard, Room 6B05 MSC-7540 Bethesda, MD 20892-7540 301/496-4401 301/402-0177	

Other HHS Offices

Office of the Inspector General (OIG) **http://www.oig.hhs.gov**	
Department of Health and Human Services OIG Hotline Attn: HOTLINE 330 Independence Avenue, SW Washington, DC 20201 800-HHS-TIPS (1-800-447-8477) e-mail: HHSTips@org.hhs.gov	Questions concerning A-133 audit requirements: National External Audit Resources Office of Audit Services 323 West 8th Street Lucas Place, Room 514 Kansas City, Missouri 64105 800/732-0679 (voice) 816/374-6714 (voice) 816/374-6727 (fax) http://harvester.census.gov/sac
Office for Human Research Protections (OHRP) **http://www.hhs.gov/ohrp/**	
The Tower Building 1101 Wootton Parkway, Suite 200 Rockville, MD 20852 301/496-7005	
Office of Research Integrity (ORI) **http://ori.dhhs.gov**	
The Tower Building 1101 Wootton Parkway, Suite 750 Rockville, MD 20852 301/443-5300 e-mail: askori@osophs.dhhs.gov	
Departmental Appeals Board (DAB) **http://www.hhs.gov/dab/**	
200 Independence Avenue, SW Hubert H. Humphrey Building, Room 637-D Washington, DC 20201 202/690-5501 e-mail: DAB@hhs.gov	
Office for Civil Rights (OCR) **http://www.hhs.gov/ocr**	
Office of Program Operations 200 Independence Avenue, SW Room 509 F Washington, DC 20201 800/368-1019	

Program Support Center Financial Management Service Division of Payment Management (DPM) http://www.dpm.psc.gov	
P.O. Box 6021 Rockville, MD 20852 301/443-9193 301/443-3586 (fax) e-mail: info@psc.dhhs.gov Find Account Representative: http://www.dpm.psc.gov/Contact.aspx	
Division of Cost Allocation (DCA) **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)	330 Independence Avenue, S.W. Cohen Building, Room 10-67 Washington, DC 20201 202/401-2808
Northeastern Field Office (Services Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Puerto Rico, the Virgin Islands, Canada and Europe)	26 Federal Plaza Room 41-122 New York, NY 10278 212/264-2069
Central States Field Office (Services Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, New Mexico, Ohio, Oklahoma, Texas and Wisconsin)	1301 Young Street Room 702 Dallas, TX 75202 214/767-3261
Western Field Office (Services Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, Australia, and Asia)	50 United Nations Plaza Room 347 San Francisco, CA 94102 415/437-7820

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