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# NIH Grants Policy Statement

## U.S. Department of Health and Human Services

### National Institutes of Health

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October 1, 2010

# Introduction

The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH grantees, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. This document also is designed to be useful to those interested in NIH grants by providing information about NIH—its organization, its staff, and its grants process. The NIHGPS is available online at http://grants.nih.gov/grants/policy/policy.htm#gps. This version includes many links within the document as well as links to some web resources outside of this document. Users are strongly encouraged to use the on-line version of this document to benefit from these links.

## NIHGPS ORGANIZATION

The NIHGPS has three parts, which allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions:

- ***Part I: NIH Grants—General Information.*** Part I (chapters 1 and 2) contains a glossary defining commonly used terms and abbreviations used throughout the document; describes NIH and its relationship to other organizations within the Department of Health and Human Services (HHS); specifies grantee, NIH, and other HHS staff responsibilities and outlines the grant application and review processes.

- ***Part II: Terms and Conditions of NIH Grant Awards.*** Part II (chapters 3-19) includes generally applicable terms and conditions (Part IIA). This part also specifies the terms and conditions that apply to particular types of grants, grantees, and activities that differ from, supplement, or elaborate on the standard terms and conditions (Part IIB). These requirements, in separate chapters, pertain to multiple PD/PI applications and awards; construction, modernization and major alteration and renovation grants; research training grants and fellowships; career development awards; modular applications and awards; conference grants, consortium agreements; grants to foreign and international organizations (and grants with substantial foreign components awarded to domestic organizations), grants to Federal institutions and payments to Federal employees; grants to for-profit organizations; and research patient care activities.

- ***Part III: Points of Contact.*** Part III (chapter 20) lists pertinent offices with their contact information.

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## CONVENTIONS

Certain conventions are followed throughout this document. The term "grant" is used to mean both grants and cooperative agreements; however, for clarity, certain sections mention both grants and cooperative agreements. The term "grantee" generally is used to refer to recipients of grants and awardees of cooperative agreements; however the terms "recipient" or "awardee" also are used. "NIH" may be used in this document to refer to the entire organization or to its component organizations, or else to contrast an action by NIH, including actions by its ICs, with an action by a grantee or other organization. A reference to "Part II (IIA or IIB)" or "Part III" without further elaboration means the corresponding part of the NIHGPS.

# SUPERSESSION

The NIHGPS was originally published with an effective date of October 1, 1998. It was subsequently revised in 2001 and 2003. This revision of the NIHGPS is an update of the 2003 publication. It applies to all NIH grants and cooperative agreements for budget periods beginning on or after October 1, 2010. It incorporates several new and modified requirements, clarifies certain policies, and emphasizes policies that require increased attention by grantees on the basis of recent developments. A number of the changes are ones that have been published since December 2003 as notices in the *NIH Guide for Grants and Contracts*; others implement recent changes in statutes, regulations, and policies. An explanation of the major changes from the December 2003 NIHGPS is included in the *NIH Guide for Grants and Contracts* notice announcing the reissuance of the NIHGPS.

# ADDITIONAL INFORMATION

The Office of Policy for Extramural Research Administration (OPERA) develops and maintains this document. Changes in statutes, regulations, or policies that take effect before the next revision of the NIHGPS will be published separately in the *NIH Guide for Grants and Contracts*. Grantees are responsible for reviewing the *NIH Guide for Grants and Contracts*, which is published on the NIH home page at http://grants.nih.gov/grants/guide/index.html, for changes and for implementing them, as appropriate. Subscribe to the *NIH Guide for Grants and Contracts* Listserv at http://grants.nih.gov/grants/guide/listserv.htm.

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# Part I: NIH Grants—General Information

This part contains a glossary defining terms and abbreviations commonly used throughout the NIHGPS; describes NIH and its relationship to other organizations within HHS; specifies grantee, NIH, and other HHS staff responsibilities; and outlines the grant application and review processes.

# 1 GLOSSARY

The glossary lists acronyms and other abbreviations used in the NIHGPS. The glossary also defines terms commonly used throughout the NIHGPS. The definitions may be amplified and additional definitions may be found throughout this document and in source documents, such as applicable statutes, grants administration regulations, and OMB circulars. This is the only location in the NIHGPS where these terms are defined. If an abbreviation used in the NIHGPS is unfamiliar, the reader should consult this list for its meaning.

## 1.1 ABBREVIATIONS

**Exhibit 1: Abbreviation and full language of acronyms used in the Grants Policy Statement**

| Abbreviation | Full Meaning of Abbreviation |
|---|---|
| A&R | Alteration and Renovation |
| ACF | Administration for Children and Families |
| ACH | Automated Clearinghouse |
| AHRQ | Agency for Healthcare Research and Quality |
| AIA | American Institute of Architects |
| AoA | Administration on Aging |
| AOR | Authorized Organization Representative |
| APAC | Annual Payback Activities Certification |
| AREA | Academic Research and Enhancement Award |
| ASHRAE | American Society of Heating, Refrigeration and Air Conditioning Engineers |
| BSO | Biological Safety Officer |
| CDA | Career Development Award |
| CDC | Centers for Disease Control and Prevention |
| CFR | Code of Federal Regulations |
| CGMO | Chief Grants Management Officer |
| CM | Construction Manager |
| CMS | Centers for Medicare and Medicaid Services |

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| Abbreviation | Full Meaning of Abbreviation |
|---|---|
| CoC | Certificate of Confidentiality |
| COR | Career Opportunities in Research Education and Training Program |
| CSR | Center for Scientific Review |
| DAB | Departmental Appeals Board |
| DCA | Division of Cost Allocation, HHS |
| DCIS | Departmental Contracts Information System |
| DEA | Drug Enforcement Administration |
| DEAS | Division of Extramural Activities Support, NIH |
| DEITR | Division of Extramural Inventions & Technology Resources, OPERA, OER, NIH |
| DES | Department of Engineering Services, NIH |
| DFAS | Division of Financial Advisory Services, NIH |
| DGCO | Division of Grants Compliance and Oversight, OPERA, OER, NIH |
| DGP | Division of Grants Policy, OPERA, OER, NIH |
| DNA | Deoxyribonucleic acid |
| DoC | Department of Commerce |
| DoD | Department of Defense |
| DoL | Department of Labor |
| DPI | Division of Program Integrity, OMA, NIH |
| DPM | Division of Payment Management, HHS |
| DRR | Division of Receipt and Referral, CSR |
| DSMB | Data and Safety Monitoring Board |
| DUNS | Data Universal Numbering System |
| EA | Environmental Assessment |
| eFSR/FFR | Electronic Financial Status Report/Federal Financial Report |
| EIN | Entity Identification Number |
| EIS | Environmental Impact Statement |
| EO | Executive Order |
| eRA | Electronic Research Administration |
| ESI | Early Stage Investigator |
| eSNAP | Electronic Streamlined Non-competing Award Process |
| F&A | Facilities and Administrative (costs) |

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| Abbreviation | Full Meaning of Abbreviation |
|---|---|
| FAC | Federal Audit Clearinghouse |
| FAR | Federal Acquisition Regulation |
| FCOI | Financial Conflict of Interest |
| FDA | Food and Drug Administration |
| FDAAA | Food and Drug Administration Amendments Act |
| FDP | Federal Demonstration Partnership |
| FEMA | Federal Emergency Management Agency |
| FFATA | Federal Funding Accountability and Transparency Act |
| FFR | Federal Financial Report (SF425) |
| FIC | Fogarty International Center |
| FICA | Federal Insurance Contributions Act |
| FOA | Funding Opportunity Announcement |
| FOI | Freedom of Information |
| FOIA | Freedom of Information Act |
| FSR | Financial Status Report (SF 269 or 269A) |
| FTR | Federal Travel Regulation |
| FWA | Federalwide Assurance |
| GeMCRIS | Genetic Modification Clinical Research Information System |
| GMO | Grants Management Officer |
| GMP | Guaranteed Maximum Price |
| GMS | Grants Management Specialist |
| GPO | Government Printing Office |
| GSA | General Services Administration |
| GWAS | Genome-wide Association Studies |
| hESC | Human Embryonic Stem Cells |
| HHS | Department of Health and Human Services |
| HIPAA | Health Insurance Portability and Accountability Act |
| HPSL | Health Professional Student Loan |
| HRSA | Health Resources and Services Administration |
| HVAC | Heating, Ventilating, and Air Conditioning |
| IACUC | Institutional Animal Care and Use Committee |
| IBC | Institutional Biosafety Committee |

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| Abbreviation | Full Meaning of Abbreviation |
|---|---|
| IBS | Institutional Base Salary |
| IC | Institute or Center |
| IDE | Investigational Device Exception |
| IHS | Indian Health Service |
| IND | Investigational New Drug |
| IPA | Intergovernmental Personnel Act |
| IPF | Institutional Profile File |
| IR&D | Independent Research and Development |
| IRB | Institutional Review Board |
| IRG | Initial Review Group |
| IRS | Internal Revenue Service |
| IVF | Invitro Fertilization |
| K award | Career Award |
| Kirschstein-NRSA | Ruth L. Kirschstein National Research Service Award |
| LWOP | Leave Without Pay |
| MARC-U*STAR | Minority Access to Research Careers Undergraduate Student Training in Academic Research Program |
| MOU | Memorandum of Understanding |
| NCRR | National Center for Research Resources |
| NCT | National Clinical Trial |
| ND | Not Discussed |
| NEARC | National External Audit Review Center, OIG |
| NEI | National Eye Institute |
| NEPA | National Environmental Policy Act |
| NFI | Notice of Federal Interest |
| NFPA | National Fire Protection Association |
| NHSC | National Health Service Corps |
| NICHD | *Eunice Kennedy Shriver* National Institute for Child Health and Human Development |
| NIDCR | National Institute of Dental and Craniofacial Research |
| NIGMS | National Institute of General Medical Sciences |
| NIH | National Institutes of Health |
| NIH MSID | NIH manuscript submission reference number |

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| Abbreviation | Full Meaning of Abbreviation |
|---|---|
| NIHGPS | National Institutes of Health Grants Policy Statement |
| NIMH | National Institute of Mental Health |
| NINR | National Institute on Nursing Research |
| NLM | National Library of Medicine |
| NoA | Notice of Award |
| NTIS | National Technical Information Service |
| OBA | Office of Biotechnology Activities, NIH |
| OCR | Office for Civil Rights, HHS |
| OEP | Office of Extramural Programs, OER, NIH |
| OER | Office of Extramural Research, NIH |
| OFCCP | Office of Federal Contract Compliance Programs, DoL |
| OFM | Office of Financial Management, NIH |
| OHRP | Office for Human Research Protections, HHS |
| OIG | Office of the Inspector General |
| OIR | Office of Intramural Research, NIH |
| OLAW | Office of Laboratory Animal Welfare, NIH |
| OMA | Office of Management Assessment, NIH |
| OMB | Office of Management and Budget |
| ONR | Office of Naval Research |
| OPERA | Office of Policy for Extramural Research Administration, OER, NIH |
| OPHS | Office of Public Health and Science |
| ORI | Office of Research Integrity, HHS |
| OSC | Other Significant Contributor |
| P.L. | Public Law |
| PA | Program Announcement |
| PAR | Program Announcement with Special Review Criteria |
| PD/PI | Program Director/Principal Investigator |
| pdf | portable document format |
| PHS | Public Health Service |
| PMC | PubMed Central |
| PMCID | PubMed Central Identification/reference number |
| PMS | Payment Management System, HHS |

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| Abbreviation | Full Meaning of Abbreviation |
|---|---|
| PO | Program Official |
| PSC | Payback Service Center, NIH, or Program Support Center, HHS |
| R&D | Research and Development |
| R&R | Research and Related |
| RePORT | Research Portfolio Online Reporting Tool |
| RFA | Request For Applications |
| RFP | Request For Proposals |
| ROTC | Reserve Officer Training Corps |
| S&W | Salaries and Wages |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SBA | Small Business Administration |
| SBC | Small Business Concern |
| SBIR | Small Business Innovation Research Program |
| SEP | Special Emphasis Panel |
| SEVIS | Student and Exchange Visitor Information System |
| SF | Standard Form |
| SII | Successor-In-Interest |
| SNAP | Streamlined Non-competing Award Process |
| SO | Signing Official |
| SPOC | State Single Point of Contact |
| SRG | Scientific Review Group |
| SRO | Scientific Review Officer |
| STTR | Small Business Technology Transfer Program |
| TVPA | Trafficking Victims Protection Act |
| U.S. | United States |
| U.S.C. | United States Code |
| USCIS | United States Citizenship and Immigration Services |
| USDA | United States Department of Agriculture |
| USPS | United States Postal Service |
| VA | Department of Veterans Affairs |
| VAMC | VA Medical Center |
| VANPC | VA-Affiliated Non-Profit research Corporation |

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| Abbreviation | Full Meaning of Abbreviation |
|---|---|
| VHA | Veterans Health Administration |
| WIC | Women, Infants and Children |

## 1.2 DEFINITIONS OF TERMS

**Exhibit 2: Definitions of terms used in the Grants Policy Statement**

| Term | Definition |
|---|---|
| acquisition cost | The cost of an asset, including the cost to put it in place. When used with equipment (capital expenditure), the term means the net invoice price of property or supplies including cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired. Other charges, such as the cost of installation, transportation, taxes, duty, or protective in-transit insurance, are included or excluded from the unit acquisition cost in accordance with the recipient's regular accounting practices. It does not include costs for rental of property or alteration and rental of real property. |
| activity code | A 3-character code used to identify a specific category of extramural research activity, applied to various funding mechanisms. NIH uses three funding mechanisms for extramural research awards: grants, cooperative agreements and contracts. Within each funding mechanism, NIH uses 3-character activity codes (e.g., F32, K08, P01, R01, T32, etc.) to differentiate the wide variety of research-related programs NIH supports. A comprehensive list of activity codes is on the NIH Web site at http://grants.nih.gov/grants/funding/ac_search_results.htm. |
| additive alternative | A use of program income earned during or after the project period that permits income that is generated under a grant to be added to funds committed to the project by the Federal awarding agency and recipient and used to further eligible project or program objectives. (See definitions for deductive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income.) |
| administrative requirements | The general business management practices that are common to the administration of all grants, such as financial accountability, reporting, equipment management, and retention of records. |
| administrative supplement | A request for (or the award of) additional funds during a current project period to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer reviewed and approved project. |
| advance payment | A payment made to a recipient before the recipient disburses the funds for program purposes. |
| allocation | The process of assigning costs to one or more cost objectives, in reasonable and realistic proportion to the benefit provided or other equitable relationship. For additional information, see Cost Considerations—The Cost Principles. |

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| Term | Definition |
|---|---|
| allowable cost | A cost incurred by a recipient that is: (1) reasonable for the performance of the award; (2) allocable; (3) in conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost or in the NoA as to the type or amount of cost; (4) consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; (5) accorded consistent treatment as a direct or indirect cost; (6) determined in accordance with generally accepted accounting principles; and (7) not included as a cost in any other federally supported award (unless specifically authorized by statute).<br><br>For additional information on each, see Cost Considerations—The Cost Principles. |
| alteration and renovation | Work that changes the interior arrangements or other physical characteristics of an existing facility or of installed equipment so that it can be used more effectively for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. See also definitions for Major A&R and Minor A&R. |
| applicable clinical trial | Applicable clinical trial is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of trials that may be subject to the registration and reporting requirements in FDAAA. Applicable clinical trials generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S., involves a drug, biologic, or device that is manufactured in the U.S. (or its territories), or is conducted under an investigational new drug application (IND). For the complete statutory definition and more detailed information see http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm. |
| applicable credit | Those receipts that offset or reduce direct or indirect costs. Typical examples of such transactions include purchase discounts, rebates, or allowances; recoveries or indemnities on losses, insurance refunds; and adjustments of overpayments or erroneous charges. |
| application | A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions. (See Application Information and Processes for detailed information about the application process, including an explanation of the types of applications.) |
| Appropriation Act | The statute that provides the authority for Federal agencies to incur obligations to and make payments out of the U.S. treasury for specified purposes. |
| approved budget | The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH and permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the NoA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget. |
| assurance | A certification by an applicant, normally included with the application or State plan, indicating that the entity is in compliance with, or that it will abide by, a particular requirement if awarded a Federal grant. |

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| Term | Definition |
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| audit resolution | The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings (that is, questioned costs). |
| authorized organization representative | The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This individual is equivalent to the signing official in the eRA Commons, i.e., holds the SO Role. |
| award | The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity. |
| awarding IC | The NIH IC responsible for the award, administration, and monitoring of grant supported activities. |
| budget period | The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes. |
| capital expenditure | The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient's regular accounting practices consistently applied regardless of the source of funds. (See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Capital Expenditures.) |
| carryover | Unobligated Federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). Obligated, but unliquidated, funds are not considered carryover. |
| change in scope | An activity whereby the objectives or specific aims identified in the approved grant application are significantly changed by the grantee after award. GMO prior approval is required for a change in scope to be allowable under an award. See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Change of Scope for additional information. |
| change of grantee organization | Transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the expiration of the approved project period (competitive segment). |
| change of PD/PI | A process, usually initiated by the grantee, whereby the federally approved PD/PI is replaced by another individual, with the approval of the GMO. |
| Chief Grants Management Officer | The Grants Management Officer within an awarding agency who is the principal Grants Officer in the agency. The Chief Grants Management Officer provides leadership to an organizational component that is responsible for the business and fiscal management of an IC's grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each awarding component has a CGMO. |

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| Term | Definition |
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| clinical research | Research with human subjects that is:<br><br>1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.<br><br>2) Epidemiological and behavioral studies.<br><br>3) Outcomes research and health services research<br><br>Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition. |
| clinical trial | A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits this definition of a clinical trial. Human subjects research to develop or evaluate clinical laboratory tests (e.g., imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test itself imposes more than minimal risk for the subjects.<br><br>Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases:<br><br>Phase I. Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).<br><br>Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety.<br><br>Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.<br><br>Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use. |
| closeout | The process by which a Federal awarding agency determines that all applicable administrative actions and all required work under an award have been completed by the grantee and the Federal awarding agency. |

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| Term | Definition |
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| Code of Federal Regulations | The codified regulations of the Federal government based on the final agency regulations published in the Federal Register. |
| cognizant agency | The Federal agency which, on behalf of all Federal agencies, is responsible for: reviewing, negotiating, and approving cost allocation plans, indirect cost rate and similar rates; monitoring non-Federal audit reports; conducting Federal audits as necessary; and resolving cross-cutting audit findings. The cognizant agency under the applicable cost principles and under OMB Circular A-133 may be different for a given recipient. |
| co-investigator | An individual involved with the PD/PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered senior/key personnel. The designation of a co-investigator, if applicable, does not affect the PD/PI's roles and responsibilities as specified in the NIHGPS, nor is it a role implying multiple PD/PI. |
| competitive revision | A request for (or the award of) additional funds during a current project period to support new or additional activities which are not identified in the current award that reflect an expansion of the scope of the grant-approved activities. Competitive revisions require peer review. |
| competitive segment | The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a renewal award. |
| conference (domestic or international) | A symposium, seminar, workshop, or any other organized and formal meeting, whether conducted face-to-face or via the Internet, where individuals assemble (or meet virtually) to exchange information and views or explore or clarify a defined subject, problem, or area of knowledge, whether or not a published report results from such meeting. |
| conference grant | A grant whose purpose is to support activities related to the conduct of a conference(s) or defined set of conference-related activities. |
| conflict of interest | Conflict of Interest is a cross-cutting issue that affects many policy areas such as peer review, financial conflict of interest, and responsible conduct of research. There are different uses of this term throughout this document. It generally means that a competing personal interest could affect, or could appear to affect, an individual's judgment or could cause the individual's impartiality to be questioned. Conflicts of Interest (actual or potential) may arise in the objective review process or in other activities or phases of the financial assistance process. See also Financial Conflict of Interest for a specific definition covering that policy area. |
| consortium agreement | A formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, 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. These agreements typically involve a specific level of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. The relationship between the recipient and the collaborating organizations is considered a subaward relationship. (See Consortium Agreements chapter in IIB.) |

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| Term | Definition |
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| 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 acquisition and off-site improvements). The construction of shell space is not allowable as a construction activity since shell space does not provide usable space for research activities. Expansion, new construction, or activities that would change the "footprint" of an existing facility (e.g., relocation of existing exterior walls, roofs, or floors, attachment of fire escapes) is considered construction. See Construction chapter in IIB. |
| consultant | An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, grantees and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants also include firms that provide professional advice or services. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Consultant Services.) |
| contact PD/PI | When multiple PD/PIs are designated, NIH requires that the applicant organization identify one of the PD/PIs as the Contact PD/PI to serve as a primary point of contact. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. See Multiple PI chapter in IIB for additional information. |
| contract | An award instrument used to acquire from a non-federal party, by purchase, lease, or barter, property or services for the direct benefit or use of the Federal government. The same term may be used to describe a vendor relationship between a recipient and another party under a grant (to acquire routine goods and services); however, the recipient may use subaward to describe the contract under a grant relationship. |
| cooperative agreement | A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities. |
| cost overrun | Any amount charged in excess of the Federal share of costs for the project period (competitive segment). |
| cost principles | The government-wide principles, issued by OMB (or, in the case of commercial organizations, the Federal Acquisition Regulation [48 CFR part 21], or, in the case of hospitals, 45 CFR part 74, Appendix E, "Principles For Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals"), on allowability and unallowability of costs under federally sponsored agreements. See Cost Considerations—The Cost Principles for additional details. |
| cost sharing | See matching or cost sharing definition. |
| cost sharing or matching alternative | An alternative use of program income whereby income accrued during the period of grant support may be used to satisfy a cost sharing or matching requirement. (See also definitions for additive alternative and deductive alternative and Administrative Requirements—Management Systems and Procedures—Program Income.) |

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| Term | Definition |
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| data and safety monitoring plan | For each NIH-supported clinical trial, NIH requires a data and safety monitoring plan that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the awarding IC for approval prior to the accrual of human subjects. |
| debarment and suspension | The actions taken by a debarring official in accordance with OMB guidance at 2 CFR part 180, "Non-procurement Debarment and Suspension," as implemented by HHS in 2 CFR part 376, to exclude a person or organization from participating in grants and other non-procurement awards government-wide. If debarred or suspended, the person or organization may not receive financial assistance (under a grant, cooperative agreement, or subaward, or contract under a grant) for a specified period of time. Debarments and suspensions carried out pursuant to 2 CFR part 376 are distinct from post-award suspension action by an awarding agency. (See also Public Policy Requirements and Objectives—Debarment and Suspension.) |
| debt collection | The process of collecting funds owed by recipients to the Federal government, which, under grants, generally are owed as a result of formal cost disallowances. |
| debt instrument | A document used to record a legal obligation of one party to pay a financial obligation to another in accordance with predetermined terms and conditions. |
| deductive alternative | An alternative for the use of program income earned during the period of grant support under which allowable costs of the project or program to be paid by the Federal government are offset by the amount of the program income. (See also definitions for additive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income.) |
| deviation | A departure on a single-case or class basis from a regulatory or policy requirement. A single-case deviation represents a request for waiver or exception sought for one grant only that arises on a case-by-case basis. A class deviation involves more than one grant for which the same type of deviation action is being requested. |
| direct costs | Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy. |
| disallowance | A charge to a grant that the Federal awarding agency determines to be unallowable in accordance with the applicable Federal cost principles or other terms and conditions contained in the award. |
| domestic organization | A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities. |
| DUNS number | A nine-digit number established and assigned by Dun and Bradstreet to uniquely identify a business entity. |

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| Term | Definition |
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| Entity Identification Number | A three-part coding scheme of 12 characters used in PMS to identify organizations and individuals. The first character identifies the recipient as an organization or an individual. The next nine characters are the Employer Identification Number. The last two characters are a suffix to provide distinction between organizational entities that are assigned a single EIN and those that have more than one. |
| early stage investigator | An individual who is classified as a New Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). See definition of New Investigator. |
| equipment | An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less. |
| Excluded Parties List System | A public database maintained by the General Services Administration which is the official government-wide system of record for debarments, suspensions, and other exclusionary actions. (see also Public Policy Requirements and Objectives—Debarment and Suspension.) |
| eRA Commons | The Electronic Research Administration (eRA) Commons is a virtual meeting place where NIH extramural grantee organizations, grantees, and the public can receive and transmit information about the administration of biomedical and behavioral research. The eRA Commons is divided into both unrestricted and restricted portions that provide for public and confidential information, respectively. |
| expanded authorities | Operating authorities provided in Federal Administrative Regulations (e.g., A-110) to grantees that waive the requirement for prior approval for specified actions. NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances thus these authorities have become the NIH Standard Terms of Award. Therefore, the term Expanded Authorities is no longer used at NIH (see Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award). |
| expiration date | Generally, the date signifying the end of the current project period, after which the grantee is not authorized to obligate grant funds. |
| facilities and administrative costs | Costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. These costs also are known as indirect costs. |
| Federal Demonstration Partnership | A cooperative initiative among some Federal agencies, including NIH, selected organizations receiving Federal funding for research, and certain professional associations. Its efforts include demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs. |
| Federal institution | A Cabinet-level department or independent agency of the executive branch of the Federal government or any component organization of such a department or agency. |
| Federal interest | When used in conjunction with the acquisition of real property, equipment, or supplies under an award (whether paid by Federal funds or satisfying some or all of a matching or cost sharing requirement), the dollar amount that is the product of the Federal share of project costs multiplied by the current fair market value of the property. |

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| Term | Definition |
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| Federal share | The amount, generally expressed both in dollars and as a percentage of the total approved budget for a project or program, whether provided as funds, property, or direct assistance provided by the Federal government. The Federal share and any non-Federal share are so noted in the NoA. |
| Federalwide Assurance | The Federalwide Assurance is the only type of new assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under a FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the terms of assurance. |
| fee | An amount, in addition to actual, allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as profit. (See Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowable Costs and Fee—Profit or Fee.) |
| financial assistance | Transfer by NIH of money or property to an eligible entity to support or stimulate a public purpose authorized by statute. |
| financial conflict of interest | A financial conflict of interest exists when the grantee's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. See 42 CFR part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought and Public Policy Requirements and Objectives—Financial Conflict of Interest. |
| for-profit organization | An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. A for-profit organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons. (Also see definition for small business concern.)<br><br>For-profit organizations also are referred to as "commercial organizations." |
| foreign component | The performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the grantee that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Foreign travel for consultation is not considered a foreign component. (See Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components chapter in IIB.) |
| foreign institution | An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PD/PI. |

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| Term | Definition |
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| full-time appointment | The number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support. |
| funding opportunity announcement | A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program. Funding opportunity announcements can be found at Grants.gov/FIND and in the *NIH Guide for Grants and Contracts*. |
| grant | A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities. |
| grant-supported project or activity | Those activities specified or described in a grant application or in a subsequent submission that are approved by an NIH IC for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out. |
| grantee | The organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The grantee is the entire legal entity even if a particular component is designated in NoA. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity. Also known as awardee or recipient. |
| Grants.gov | Grants.gov (http://www.grants.gov/) has been designated by the Office of Management and Budget as the single access point for all grant programs offered by 26 Federal grant-making agencies. It provides a single interface for agencies to announce their grant opportunities and for all applicants to find and apply for those opportunities. |
| Grants Management Officer | An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards. See also Chief Grants Management Officer definition. The Chief Grants Management Officer is the principal Grants Management Officer who provides leadership to an organizational component that is responsible for the business and fiscal management of an IC's grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. |
| Grants Management Specialist | An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award. |

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| Term | Definition |
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| hospital | A non-profit or for-profit hospital or a medical care provider component of a non-profit organization (for example, a foundation). The term includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria. |
| human subject | A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. (See Public Policy Requirements and Objectives—Human Subjects Protections.) |
| impact/priority score | The impact/priority score is the rating which is assigned to an individual application by an SRG, and designates the reviewers' assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of established review criteria. The impact/priority score is one mechanism by which the SRG makes a recommendation to the funding component concerning the application's scientific and technical merit. Impact/priority scores may be numeric (10 – 90) or alphabetical (ND, for example). |
| investigational new drug | A new drug or biological drug that is used in a clinical investigation. |
| indirect costs | See facilities and administrative costs definition. |
| innovation | Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of innovation would be new medical or biological products for improved value, efficiency, or costs. |
| Institute or Center | The NIH organizational component responsible for a particular grant program or set of activities. The terms "NIH IC," or "awarding IC" are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award. |
| Institutional Animal Care and Use Committee | The *PHS Policy on Humane Care and Use of Laboratory Animals* incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the grantee to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). IACUC review and approval is required for all PHS supported activities involving live vertebrate animals prior to funding. |
| institutional base salary | The annual compensation paid by an organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages.) |

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| Term | Definition |
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| Institutional Review Board (IRB) | An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. |
| intangible property | Property that does not have physical existence. The term includes copyrights, patents, and other intellectual property generated or developed under awards. It also includes copyrights for which assignments of rights are acquired under awards; patents and other intellectual property for which ownership is acquired under awards; loans, notes, and other debt instruments (even if considered tangible for some purposes); lease agreements; and stock and other instruments of property ownership. |
| Intergovernmental Personnel Act (IPA) | The Intergovernmental Personnel Act Mobility Program provides for the temporary assignment of personnel between the Federal Government and state and local governments, colleges and universities, Indian tribal governments, federally funded research and development centers, and other eligible organizations. The goal of the Intergovernmental Personnel Act mobility program is to facilitate the movement of employees, for short periods of time, when this movement serves a sound public purpose. |
| international organization | An organization that identifies itself as international or intergovernmental and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States. |
| invention reporting | The requirement pursuant to 37 CFR part 401 that recipients of contracts, grants or cooperative agreements fully disclose any subject inventions made during the performance of work under a funding agreement in order to protect the Federal government's rights. |
| investigator-initiated research | Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees. |
| IPF number | Institutional Profile File (IPF) number is a unique number used by NIH for tracking/reporting awards to grantee institutions. |
| Just-in-Time | NIH policy allows the submission of certain elements of a competing application to be deferred until later in the application process, after review when the application is under consideration for funding. Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. Through this module, institutions can electronically submit the information that is requested after the review, but before award. See Completing the Pre-Award Process—Just-In-Time Procedures for additional information. |
| liquidated damages | An amount defined in a contract and chargeable against funds due to the contractor for each day the contractor fails to complete the project beyond the contract completion date. |

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| Term | Definition |
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| Major A&R | An A&R project under a grant whose primary purpose is other than construction or modernization, including a project involving modernization, improvement or remodeling, exceeding $500,000 in direct costs awarded for the project. Major A&R may include improvement, conversion, rearrangement, rehabilitation or remodeling. Major A&R does not apply to minor alterations, renovations or repairs funded under a research project grant or alterations or renovations funded under an NIH center grant. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants. |
| matching or cost sharing | The value of third-party in-kind contributions and the portion of the costs of a federally assisted project or program not borne by the Federal government. Matching or cost sharing may be required by statute or program regulation. Costs used to satisfy matching or cost-sharing requirements are subject to the same policies governing allowability as other costs under the approved budget. |
| mechanism | Extramural research awards are divided into three main funding mechanisms: *grants, cooperative agreements* and *contracts.* A funding mechanism is the type of funded application or transaction used at the NIH. Within each funding mechanism NIH includes programs. Programs can be further refined by specific activity codes. |
| merger | A legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for the recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change will apply. |
| Minor A&R | An A&R project under a grant whose primary purpose is other than construction or modernization, including a project involving improvement or remodeling, which does not exceed $500,000 in direct costs. Minor A&R is not an allowable activity or cost under grants to individuals or grants for limited purposes, such as grants in support of scientific meetings (conference grants). Routine maintenance and repair of the organization's physical plant or its equipment is not considered A&R; these types of costs are typically treated as F&A costs. |
| modernization | Alteration, renovation, remodeling, improvement, expansion, and/or repair of an existing building and the provision of equipment necessary to make the building suitable for use for the purposes of a particular program. The entire purpose of the modernization grant is to modernize biomedical research facilities and not to support the conduct of any research. |
| modular application | A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review of the application, award, and post-award administration. |
| monitoring | A process whereby the programmatic and business management performance aspects of a grant are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources. |
| name change | An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a grantee. |

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| Term | Definition |
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| new investigator | A PD/PI who has not previously competed successfully as a PD/PI for a substantial independent research award is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains his or her status as a New Investigator. A complete list of NIH grants that do **not** disqualify a PD/PI from being considered a New Investigator can be found at http://grants.nih.gov/grants/new_investigators/resources.htm.<br><br>See also the definition of Early Stage Investigator. |
| no-cost extension | An extension of time to a project period and/or budget period to complete the work of the grant under that period, without additional Federal funds or competition. See NIH Standard Terms of Award and Prior Approval Requirements. |
| non-competing continuation application/award | A financial assistance request (in the form of an application or progress report) or resulting award for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applicants. |
| non-Federal share | When cost sharing or matching is required as a condition of an award, the portion of allowable project/program costs not borne by the Federal government. |
| non-profit organization | Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Non-profit organizations include institutions of higher education, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments). |
| Notice of Award | The official, legally binding document, signed (or the electronic equivalent of signature) by a Grants Management Officer that:<br><br>(1) notifies the recipient of the award of a grant;<br><br>(2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and,<br><br>(3) provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system. |
| obligations | The amounts for which the recipient has made binding commitments for orders placed for property and services, contracts and subawards, and similar transactions during a funding period that will require payment during the same or a future period. |
| objective review | A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is performed by persons expert in the field of endeavor for which support is requested, and is intended to provide advice to the individuals responsible for making award decisions. (See also The Peer Review Process.) |

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| Term | Definition |
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| OMB Circulars | Government-wide guidance issued to Heads of Federal agencies by the Director of OMB. OMB Circulars directly pertinent to grants include the following:<br><br>• cost principles (OMB Circular A-21, OMB Circular A-87, and OMB Circular A-122). See Cost Considerations—The Cost Principles for additional information;<br>• uniform administrative requirements (OMB Circular A-102 and OMB Circular A-110);<br>• audit requirements for non-profit organizations (OMB Circular A-133). See Monitoring—Audit for additional information.<br><br>Some (but not all) of these OMB Circulars have been reissued in Title 2 of the Code of Federal Regulations. |
| organization | A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement. |
| other significant contributors | Individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition. |
| other support | Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts. |
| parent announcement | NIH-wide FOA enabling applicants to electronically submit an investigator-initiated grant application for a specific activity code, e.g., Research Project Grant (Parent R01). |
| payback | Requirement that the recipient of a NRSA postdoctoral fellowship engage in qualified research or teaching activities for a length of time equal to the period of NRSA support received. Only the first year of training incurs a payback obligation. In general, payback activity must involve at least 20 hours per week and be conducted over 12 consecutive months; special exceptions may be considered on a case-by-case basis. See Ruth L. Kirschstein National Research Service Awards—Payback for additional information. |
| Payment Management System | The HHS centralized grants payment system operated by the Division of Payment Management, Program Support Center. Most HHS (and some other Federal government agencies') recipients receive grant payments through this system. |
| peer review | A form of objective review required by statute. It is an assessment of scientific or technical merit of applications by individuals with knowledge and expertise equivalent (peer) to that of the individuals whose applications for support they are reviewing, that is, reviewers who are the professional equals of the PD/PI for the proposed project and who often are engaged or were previously engaged in comparable activities. See The Peer Review Process for additional information. |

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| Term | Definition |
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| person months | The metric for expressing the effort (amount of time) PD/PI(s), faculty and other senior/key personnel devote to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year, academic year, and/or summer term; and the organization's definition of such. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment. |
| Phase III clinical trial | As defined by NIH, a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included. (See also clinical trial definition.) |
| pre-award costs | Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant's own risk, for otherwise allowable costs. |
| prior approval | Written approval from the designated GMO required for specified post-award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements). |
| profit | See definition for fee. |
| program | A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs that carry out their missions through the award of grants or cooperative agreements to other organizations. |
| Program Director/ Principal Investigator | The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the applicant organization, or as appropriate, to a collaborating organization for the proper conduct of the project or program including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI. |
| program income | Gross income earned by the grantee organization that is directly generated by the grant-supported project or activity or earned as a result of the award (see Administrative Requirements—Management Systems and Procedures—Program Income). |
| Program Official/ Program Officer/ Project Officer | The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant. |

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| Term | Definition |
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| progress report | Periodic, usually annual, report submitted by the grantee and used by NIH to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report. This report may also be called the non-competing continuation progress report. |
| project/ performance site | Location(s) of where the work described in the research plan will be conducted. |
| project period | The total time for which Federal support of a project has been programmatically approved as shown in the NoA; however, it does not constitute a commitment by the Federal government to fund the entire period. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a renewal award(s), and extensions. |
| real property | Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment. |
| recipient | The organizational entity or individual receiving a grant or cooperative agreement. See also definition for grantee. |
| renewal | A request for assistance to extend for one or more additional budget periods a project period that would otherwise expire. Renewal applications compete for funds with other renewal applications, revised (supplemental) and new applications. The previous NIH term was "competing continuation." |
| research | A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed "research and development." |
| Research Administrator | The Research Administrator acts as a local agent of the SOR and/or PD/PIs providing day-to-day grant-related support. See also Roles and Responsibilities—Grantee Staff. |
| research misconduct | Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.<br>1. Fabrication is making up data or results and recording or reporting them.<br>2. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record.<br>3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.<br>4. Research misconduct does not include honest error or honest differences of opinion. |
| research patient care costs | Costs of routine and ancillary services provided by hospitals to participants in research protocols. |

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| Term | Definition |
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| responsible party | Responsible party is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to refer to the entity or individual who is responsible for registering a clinical investigation and submitting clinical trial information to the Clinical Trial Registry Data Bank. Responsible party is defined by the law as the sponsor of the clinical trial or the PD/PI of such clinical trial if so designated by a sponsor, contractor, grantee, or awardee, so long as the PD/PI is responsible for conducting the trial and has sufficient data rights. For the complete statutory definition and more detailed information see http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm. |
| resubmission application | An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. Applicants must make significant changes to the application and can only resubmit once the summary statement is available. Additional policies on resubmissions can be found in the applicable Application Instruction Guide. The previous NIH term was "revision." A resubmission has a suffix in its application identification number, e.g., A1. |
| revision application | As defined in the Federalwide SF424 (R&R): An application that proposes a change in 1) the Federal Government's financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. Note in general for NIH applicants, #2 would not require the submission of another application. NIH grantees use revision applications to request an increase in support in a current budget period for expansion of the project's approved scope or research protocol. Applicants must apply and undergo peer review. The previous NIH term was "competing supplemental." NOTE: The former NIH term "revision," is now "resubmission". A revision has a suffix in its application identification number; e.g., S1. |
| scientific review group (SRG) | A scientific review group (SRG) is a peer review committee group of primarily non-government experts (peer reviewers), qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review, to evaluate and give expert advice on the scientific and technical merit of the applications. No more than one-fourth of the members of any SRG may be Federal employees, as noted in 42 CFR part 52(h). |
| scientific review officer (SRO) | A scientific review officer (SRO) is the NIH official who serves as the designated Federal official having legal responsibility for managing the peer review meeting, the procedures for evaluating the applications assigned to the SRG and the determinations and management of conflicts of interest, as noted in 42 CFR part 52(h). |
| scope of work | The aims, objectives, and purposes of a grant; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the grant's objectives. This includes the research or training plan included with the original grant application, along with any approved modifications. |
| senior/key personnel | The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. "Zero percent" effort or "as needed" is not an acceptable level of involvement for senior/key personnel. |

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| Term | Definition |
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| significant rebudgeting | A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope. |
| small business concern | A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the SBA at 13 CFR part 121. |
| State government | The government of any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. For purposes of NIH grants, federally recognized Indian tribal governments generally are considered State governments. State institutions of higher education and State hospitals are not considered State governments for HHS's general administrative requirements for grants and the NIHGPS. |
| stipend | A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee. |
| subaward | A legal instrument by which a recipient provides funds (or property in lieu of funds) to an eligible subrecipient (or a lower-tier transaction) to perform a substantive portion of the grant-supported program or project. The term includes such financial assistance when provided by any legal agreement (even if the agreement is called a contract) but does not include any form of assistance which is excluded from the definition of grant, including the recipient's procurement of property or services needed to carry out the project or program. The term includes consortium agreements. |
| subrecipient | A party that receives a subaward from a recipient or another subrecipient under a Federal financial assistance award and is accountable to the recipient or subrecipient for the use of the Federal funds provided by the subaward. |
| successor-in-interest | Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the grantee or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change. |
| supplies | All personal property excluding equipment, intangible property, debt instruments, and inventions of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement ("subject inventions"), as defined in 37 CFR part 401, "Rights to Inventions Made by Non-profit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements." |

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| Term | Definition |
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| suspension | Temporary withdrawal of a grantee's authority to obligate grant funds, pending either corrective action by the grantee, as specified by NIH, or a decision by NIH to terminate the award. This meaning of the term suspension differs from that used in conjunction with the debarment and suspension process (see Public Policy Requirements and Objectives—Debarment and Suspension and Administrative Requirements—Enforcement Actions). |
| termination | Permanent withdrawal by NIH of a grantee's authority to obligate previously awarded grant funds before that authority would otherwise expire, including the voluntary relinquishment of that authority by the grantee. |
| terms and conditions of award | All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The NoA may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the Federal government's interests. |
| total project costs | The total allowable costs (both direct costs and F&A costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement. |
| unliquidated obligation | (1) For reports prepared on a cash basis, the amount of obligations incurred by the recipient that has not been paid; or<br><br>(2) For reports prepared on an accrued expenditure basis, the amount of obligations incurred by the recipient for which an outlay has not been recorded. |
| United States | The 50 States, territories, and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia. |
| unobligated balance | The portion of the funds authorized by the Federal agency for expenditure by the recipient that has not been obligated by the recipient. |
| withholding of support | A decision by NIH not to make a non-competing continuation award within the current competitive segment. |

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# 2 THE NATIONAL INSTITUTES OF HEALTH AS A GRANT-MAKING ORGANIZATION

NIH is the steward of medical and behavioral research for the Nation. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. NIH operates under the general policy guidance of the Department in carrying out its mission, which is accomplished through the conduct and support of biomedical and behavioral research, research training, research infrastructure, and communications. These efforts take place intramurally (primarily at NIH) and extramurally (through grants, cooperative agreements, and contracts awarded to institutions of higher education, governmental organizations, non-profit research organizations, for-profit organizations, and individuals). NIH also works closely with other HHS components and other Federal departments and agencies. HHS components include SAMHSA, FDA, CDC, IHS, AHRQ, HRSA, ACF, AoA, OPHS, and CMS, among others.

HHS develops, issues, and maintains regulations that govern the Department's grants process. Among these are the regulations that implement the OMB Circular A-102 common rule, applicable to grants to State, local, and Indian tribal governments, and OMB Circular A-110 (relocated to 2 CFR part 215), applicable to grants to institutions of higher education, hospitals, and other non-profit organizations. These regulations are codified at 45 CFR part 74 (Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments, and Indian Tribal Governments) and 45 CFR part 92 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments). Although the government-wide requirements do not cover grants to for-profit organizations, HHS has included them in the coverage of 45 CFR part 74. The above regulations provide the framework for the terms and conditions of NIH awards as specified in Part II.

NIH is organized into ICs, which have their own mission and functions, separate appropriations, and statutory authorities. The ICs that award grants and their points of contact are listed in Part III. Although the ICs operate under the same general grant process and requirements, applicants and grantees need to be aware of differences that may exist. This information may be obtained from NIH IC staff. The policies and procedures generally applicable to NIH grants are set forth in the NIHGPS.

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## 2.1 ROLES AND RESPONSIBILITIES

NIH, as a Federal grantor agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for grantee organizations.

The following subsections highlight the major functions and areas of responsibility of Federal and grantee staffs. NIH recognizes that additional staff members in a number of different organizations may be involved in grant-related activities; however, this section details only the major participants representing the Federal government and the grantee. The responsibilities of CSR staff members, who are involved only in the initial review phase of the peer review process, are described in The Peer Review Process—Initial Review—Responsibilities. The responsibilities of other offices, such as OHRP, are described in Part II as applicable.

### 2.1.1 NIH and HHS Staff

The roles and responsibilities of NIH and HHS participants are as follows:

- ***Grants Management Officer.*** The GMO whose name appears in the NoA is the NIH official responsible for the business management and other non-programmatic aspects of the award. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to applicants and grantees, including interpretation of grants administration policies and provisions; and administering and closing out grants. The GMO works closely with his or her counterparts in other NIH ICs and with the designated PO. The GMO is the focal point for receiving and acting on requests for NIH prior approval or for changes in the terms and conditions of award, and is the only NIH official authorized to obligate NIH to the expenditure of Federal funds or to change the funding, duration, or other terms and conditions of award. A Chief Grants Management Officer is the principal GMO who provides leadership to an organizational component that is responsible for the business and fiscal management of the ICs grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each awarding component has a CGMO.

- ***Grants Management Specialist.*** The GMS whose name appears in the NoA is an agent of the GMO and is assigned responsibility for the day-to-day management of a portfolio of grants.

- ***Program Official.*** The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with CSR/IC SROs; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the GMO. The PO and the GMO work as a team on many of these activities.

- ***Scientific Review Officer.*** SROs are health science administrators who manage the activities of SRGs, including CSR study sections. For the SRG for which he or she is responsible, the SRO reviews applications for completeness and conformity to requirements, ensures that adequate numbers of reviewers with appropriate expertise are available for application review, assigns applications to individual reviewers as discussion leaders and for preparation of written critiques, and serves as the overall point of contact with applicants during the initial phase of the peer review process, i.e., until the conclusion of the SRG meeting.

- ***Other NIH, HHS and Federal Agency Staff.*** In addition to the GMO and PO, the grantee may be required to interact with other NIH or HHS staff members or offices with respect to its organization-wide systems and/or individual transactions. These include the office responsible for negotiating F&A costs and research patient care rates, typically the cognizant DCA office, ONR, or DFAS; OIG; OHRP; ORI; OLAW; and OPERA. Staff members in these offices generally coordinate with the GMO, but they are responsible for discrete areas of specialization and are not required to channel their communications with the grantee through the GMO. Part III includes a list of these organizations and their addresses and telephone numbers. ONR is the cognizant agency for negotiation of F&A costs for some NIH grantees.

### 2.1.2 Grantee Staff

Overall responsibility for successfully implementing an NIH grant is a shared responsibility of the PD/PI(s), the AOR, and the Research Administrator. As key members of the grant team, they respectively

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lead the scientific and administrative aspects of the grant. While communications can be conducted with Research Administrators and other institutional staff, NIH staff members conduct official business only with the designated PD/PI(s) and AORs. The roles and responsibilities of grantee participants are as follows:

- ***Authorized Organization Representative.*** The AOR is the designated representative of the grantee organization in matters related to the award and administration of its NIH grants, including those that require NIH approval. The AOR should ascertain and assure that the materials the applicant organization are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used by other individuals in the preparation and submission of a similar grant application. In signing a grant application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the grant application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the grant-supported project or activities resulting from the application. (Also see Legal Implications of Applications.) This individual also is responsible to NIH for ensuring that the organization complies with applicable Federal laws and regulations, including required certifications and assurances, its application, and the terms and conditions of individual awards. For applications submitted electronically through Grants.gov, the signature of the AOR is documented as part of the electronic submission process and is authenticated through the Grants.gov registration process. In the eRA Commons, this individual holds the Signing Official role. Although NIH requires that the grantee organization designate such an official, NIH does not specify the organizational location or full set of responsibilities for this official.

- ***Program Director/Principal Investigator.*** A PD/PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award. The applicant organization may designate multiple individuals as PD/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one identified PD/PI on an application diminishes neither the responsibility nor the accountability of any individual PD/PI.

  When a single PD/PI is designated, that individual is not required to be an employee of the applicant organization. However, because the grant, if awarded, is made to the organization, the applicant organization must have a formal written agreement with the PD/PI that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PD/PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant, if awarded.

  When multiple PD/PIs are designated, NIH requires identification of one PD/PI who will be designated as the Contact PD/PI. This person is responsible for communication between the PD/PIs and the NIH. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. They are not required to be an employee of the applicant organization. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. This same principle applies to all PD/PIs at the applicant organization; e.g., they need not be employees; however the applicant organization must have a formal written agreement in place.

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When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but need not be employees. Any consortium agreement must address the unique aspects to these individuals holding the PD/PI role.

PD/PIs are members of the grantee team responsible for ensuring compliance with the financial and administrative aspects of the award. They work closely with designated officials within the grantee organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. NIH encourages PD/PIs to maintain contact with the NIH PO with respect to the scientific aspects of the project and the GMO/GMS concerning the business and administrative aspects of the award. The NIH staff contacts list located at http://grants.nih.gov/grants/staff_list_grants_admin.htm#ics includes contact information for NIH grants management and program staff at each IC.

- ***Research Administrator.*** The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. Depending on the structure of the organization, this individual can be located centrally or within an organizational component such as a Department.

## 2.2 ERA COMMONS

eRA Commons is an online interface where grant applicants, grantees and federal staff at NIH and grantor agencies are able to conduct their research administration business electronically as well as access and share administrative information relating to research grants. While applicants use Grants.gov to find and apply for grants; the eRA Commons retrieves the application or proposal information from Grants.gov, compiles it into a consistent application format and makes then it available to applicants and NIH staff for electronic research administration purposes.

Access to the eRA Commons is vital for all steps in the NIH grant administration process. Following application submission, the eRA Commons becomes the primary site for accessing grant information such as Institute/Center assignments, review outcomes, Summary Statements, and Notices of Award. The eRA Commons also provides electronic business processes such as Internet Assisted Review, submission of Just-In-Time material, submission of electronic SNAP progress reports (eSNAP), submission of Financial Reports (FSRs/FFRs), submission of notification of extensions without funds, and submission of Closeout documents. Appropriate user roles are assigned to registered individuals depending on the responsibilities assigned to them by the grantee organization.

### 2.2.1 eRA Commons Registration

An organization and PD/PI(s) must complete a **one-time** registration in the Commons. Institutional/organizational officials are responsible for registering PD/PI(s) in the eRA Commons. PD/PI(s) should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: Organizations registering in the eRA Commons for the first time should allow 2-4 weeks to complete the registration process.

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### 2.2.1.1 eRA Commons Registration for the Organization

Prospective applicant organizations should also see Legal Implications of Applications before beginning the eRA Commons registration process.

Organizations may verify their current registration status by accessing the "List of Grantee Organizations Registered in eRA Commons" at http://era.nih.gov/commons/quick_queries/index.cfm#commons. This listing can be accessed without logging into the Commons. The list includes organization name and location, the NIH-assigned IPF Code, and any DUNS number that has been stored in the institutional profile for that organization.

To register an Organization in the eRA Commons an AOR should follow the procedures found on the eRA Commons homepage at https://commons.era.nih.gov/commons/ under the link "Grantee Organization Registration."

Once an organization is registered, information in the Institutional Profile can be maintained through the Commons.

During this registration process, NIH may make a preliminary assessment of applicant organization eligibility. Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH may deny registration if an organization is determined ineligible.

Foundations that represent already existing grantee organizations, or a newly formed consortium where the consortium members are already individually recognized as NIH grantee organizations present unique and complex situations and should contact DGP, OPERA before attempting to separately register as a new applicant organization.

### 2.2.1.2 eRA Commons Registration for the PD/PI

The individual(s) designated as the PD/PI(s) on the application must also be registered in the Commons. The PD/PI(s) must hold a PD/PI eRA Commons role **and** be affiliated with the applicant organization. **The initial registration must be done by an AOR who has the SO role in the Commons or other authorized accounts administrators at the organization.** However, after the initial registration process is complete, it becomes the responsibility of each individual to maintain the information in his/her personal profile.

Designating the PD/PI role in the eRA Commons provides the individual with the administrative authority needed to see pertinent information regarding an application (e.g., summary statements, scores, electronic submission status, etc.). The PD/PI role within the eRA Commons is necessary to complete the grant application process, to view the priority score and summary statement, and if an award is made, to complete required post-award actions such as submission of a progress report. The PD/PI may delegate certain authorities to other individuals.

Users should only have one PD/PI eRA Commons account. If the PD/PI has already been registered in eRA Commons by an organization other than the organization submitting an application, a separate eRA Commons registration with the submitting organization is not necessary. However, the submitting organization must take steps to affiliate the individual with that organization so that the individual can view and access data records for those applications.

For more information on the features of the eRA Commons, including links to resources such as user guides and frequently asked questions, see the eRA Commons webpage at: http://era.nih.gov/commons/index.cfm.

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#### 2.2.1.3 eRA Commons Registration for Individuals Serving in a Postdoctoral Role

Any individual with a postdoctoral role who participates in a NIH-funded project for at least one person month or more must also be registered in the eRA Commons with the Postdoc Role. This is required regardless of whether salary is actually charged to the project. For individuals supported on a particular research grant, this could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions. Note, this eRA Commons Postdoc role should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions.

## 2.3 APPLICATION INFORMATION AND PROCESSES

This section provides an overview of NIH's grant support mechanisms, types of entities eligible to receive grants, types of applications, types of funding opportunities, legal implications of applications, policies affecting application preparation and submission, application forms, application receipt information and deadlines, fraud, waste and abuse of NIH grant funds, and availability and confidentiality of application information.

### 2.3.1 Support Mechanisms

NIH ICs award grants under multiple programs and subprogram initiatives and use a variety of support mechanisms. NIH grants may be distinguished by purpose, type of recipient, amount, or other characteristics. One method NIH uses to differentiate the various support mechanisms is activity coding that indicates the category and specific form of support (e.g., R01, F32, P01, R43). The applicability of requirements may vary for different activity codes. Some of the distinctions also are significant for purposes of applying Part II. NIH ICs may vary in the way they use specific activity codes; not all ICs accept applications for all types of grant programs and may apply specialized eligibility criteria. A comprehensive list of activity codes is available at http://grants.nih.gov/grants/funding/ac_search_results.htm.

### 2.3.2 Eligibility

In general, NIH grants may be awarded to organizations that are domestic or foreign, public or private, or non-profit or for-profit. Eligible organizations include governments, including Federal institutions, institutions of higher education, other non-profit organizations, hospitals, and, in rare occasions, individuals (see Completing the Pre-Award Process—Determining Applicant Organization Eligibility). Any special criteria for applicant eligibility or requirements concerning the qualifications of the PD/PI or other staff or participants will be specified in the FOA, program guidelines, or other publicly available documents. Part IIB includes information on fellow and trainee eligibility.

### 2.3.3 Types of Award Instruments

NIH uses several different extramural award instruments in support of its mission. NIH grants and cooperative agreements are financial assistance instruments. Under a cooperative agreement, NIH expects to be substantially involved in carrying out the project. Grants are used both for investigator-initiated research and for more targeted research. Cooperative agreements generally do not result from investigator-initiated applications. The NIHGPS pertains to grants and cooperative agreements; however, NIH may apply terms and conditions that differ from those in the NIHGPS consistent with the nature of its involvement under cooperative agreements.

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## 2.3.4 Types of Applications

In the NIH grants process, five types of applications are used most frequently. The first four application types described below are considered "competing" because, through the peer review process, the application must compete for available funding with other applications.

- ***New Application (Type 1).*** A request for financial assistance for a project or activity that is not currently receiving NIH support and must compete for support. A new application is being submitted for the first time.

- ***Renewal (Type 2).*** A request for additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be fully developed as though the applicant is applying for the first time.

- ***Revision (Type 3).*** A request for an increase in support in a current budget period for expansion of the project's approved scope or research protocol. The request may specify budgetary changes required for the remainder of the project period as well as for the current budget period. Applications for revisions are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. A revision application should not be submitted until after the original application has been awarded and may not extend beyond the term of the current award period. A revision application must have the same title as the currently funded grant. (A Type 3 prefix also refers to a request/award for a non-competing administrative supplement [see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Need for Additional NIH Funding without Extension of Budget and Project Period.]).

- ***Resubmission.*** An unfunded application that the applicant has modified following initial review and resubmitted for new consideration. NIH allows only one resubmission application but does not restrict that submission to any timeframe. Before a resubmission application can be submitted, the PD/PI must have received the summary statement from the previous review. A resubmission application may be submitted for any of the three preceding types of applications. See Application Information and Processes—Policies Affecting Applications for other policies affecting Resubmissions.

- ***Non-Competing Continuation Progress Report (Type 5).*** A non-competing progress report is required to continue support of a PHS grant for the second or subsequent budget period within an approved competitive segment (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

NIH uses the numbers shown in parentheses as prefixes to distinguish the application types and any resulting awards (e.g., 5R0198765-02 is a non-competing continuation progress report).

## 2.3.5 Types of Funding Opportunity Announcements (FOAs)

The majority of applications submitted to NIH under the categories of research and research training (including fellowships) are investigator-initiated. NIH accepts applications on the application due dates noted on the submission schedule. NIH generally reviews applications in three review cycles per year; however any variations in schedule will be noted in the FOA. Some ICs review applications for Institutional National Research Service Awards (T32) only once a year; such information is generally found in a particular FOA. The schedules for submission, review, and award of investigator-initiated applications are available at http://grants.nih.gov/grants/funding/submissionschedule.htm.

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***Funding Opportunity Announcement (FOA).*** A FOA is a publicly available document in which a Federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. FOAs may be program announcements, requests for applications, notices of funding availability, solicitations, or other identifiers depending upon the agency and type of program. All applications must be submitted in response to a FOA regardless if the submission is electronically or on paper. FOAs include information to allow prospective applicants to determine whether to apply.

NIH FOAs primarily fall into the categories of Program Announcements, Request for Applications and Parent Announcements. While individual announcements will continue to carry an announcement number reference to PA or RFA, all announcements are FOAs. This general term is used to reference any type of funding announcement. NIH uses the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

- ***Program Announcement (PA).*** A PA is a formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time using standard peer review processes. NIH may also make funds available through PARs (PAs with special receipt, referral, and/or review considerations) and PASs (PAs with set-aside funds).

  PAs may be used for any support mechanism other than construction awards. Unless otherwise specified in the PA, new applications (and associated renewal and revision applications) submitted in response to PAs are treated as investigator-initiated. PAs also are used to annually solicit applications for the SBIR and STTR programs. Those applications must be received by the dates specified in the PA.

- ***Request for Applications (RFA).*** An RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s). For cooperative agreements, the RFA will describe the responsibilities and obligations of NIH and awardees as well as joint responsibilities and obligations. Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

- ***Parent Announcements.*** Electronic submission of applications requires that applications must be associated with a specific FOA. Therefore, NIH omnibus parent announcements are provided for applicants to submit investigator-initiated (unsolicited) applications. Responding to such an omnibus or umbrella parent FOA ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. This process in no way diminishes the interest of NIH ICs in investigator-initiated, unsolicited research grant applications. Parent announcements are NIH-wide, but some ICs may limit their participation; therefore prospective applicants should check the announcement to determine IC participation. For institute-specific opportunities in a particular area of science, search the *NIH Guide for Grants and Contracts*.

All NIH FOAs are published in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/index.html) and on Grants.gov under Find Grant Opportunities (http://www.grants.gov/applicants/find_grant_opportunities.jsp). NIH may develop areas of high priority or special research interest and use a special announcement to stimulate submission of applications in

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those areas. These announcements are also published as FOAs in the *NIH Guide for Grants and Contracts*.

## 2.3.6 Legal Implications of Applications

An applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates in order to be considered for support. The signature of an AOR on the application certifies that the organization will comply with all applicable assurances and certifications referenced in the application. The applicant organization is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application, including the F&A cost (indirect cost) rate. The AOR's signature further certifies that the applicant organization has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application.

Applicants for and recipients of NIH grant funds, whether such funds are received through a grant, indirectly under a contract or consortium agreement, or by a fiscal agent acting on another organization's behalf, or as student assistance under a training grant, are responsible for and must adhere to all applicable Federal statutes, regulations, and policies, including income tax regulations. Questions concerning the applicability of income tax regulations to grant funds should be directed to the IRS. The applicant also is expected to be in compliance with applicable State and local laws and ordinances.

Applicants may be required to provide proof of organizational eligibility (such as proof of non-profit status), trainee or fellow eligibility and citizenship, or other eligibility information. Applications also must demonstrate compliance (or intent to comply), through certification or other means, with a number of public policy requirements. The more significant of the public policy requirements for the purpose of peer review are those concerning research involving human subjects; inclusion of both genders, members of minority groups, and children in clinical research; and research involving live vertebrate animals. Part II details public policy requirements and cost and administrative policies.

There are times when an institution desires to use a Foundation or other similar organization to provide administrative services for NIH grants. These situations are often complex and each situation is unique when determining which organization is the appropriate applicant institution. Foundations, particularly those associated with institutions already recognized as NIH grantee organizations, should contact DGP, OPERA before attempting to separately register as an applicant organization.

Similarly, when new consortiums are formed where the consortium members are already separately recognized as NIH grantee organizations, DGP, OPERA should be contacted before attempting to separately register as a new applicant organization.

## 2.3.7 Policies Affecting Applications

Application information to be submitted typically includes a project description, budget and budget justification, biographical sketches of senior/key personnel, and other information specified in the application instructions, in the announcement, and/or in program guidelines, if any. Applicants should consult the cost principles and general administrative requirements for grants pertaining to their organizational type in order to prepare the budget and complete other parts of the application. This section describes NIH policies that affect application preparation and/or submission. Specific details on application content are addressed in application instructions and specific FOAs. Any significant change to the application post-submission must be reported immediately to the appropriate NIH official.

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### 2.3.7.1 Applications That Include Consortium/Contractual F&A Costs

For FOAs that include a direct cost limit, NIH policy excludes consortium/contractual F&A when determining if an applicant is in compliance with the direct cost limitation. This policy extends to all solicited and investigator-initiated applications and to all active announcements (Request for Applications and Program Announcements), involving consortium/contractual F&A costs, regardless of budget amount or budget format (e.g., modular and non-modular). While consortium F&A costs may be requested and awarded, applicants should not consider these costs when determining if a budget exceeds a direct cost limit.

This policy impacts eligibility to submit a modular budget. The modular budget format is used for applications requesting $250,000 or less in direct costs per year. Consortium/contractual F&A costs are not factored into this direct cost limit; however, they may be requested in addition to the $250,000.

This policy also impacts applications requesting a budget of $500,000 direct costs or more for any year. These applications require prior approval from Institute/Center staff; however, the limit is exclusive of any consortium F&A costs. It does not affect any specific FOA that includes a total cost limit.

This policy does not affect the SBIR and STTR programs since the statutory budget guidelines are based on total costs, not direct costs.

### 2.3.7.2 Acceptance for Review of Unsolicited Applications Requesting $500,000 or More in Direct Costs

Any applicant requesting $500,000 or more in direct costs (excluding consortium F&A costs) in any one budget period is required to contact the IC PO, in writing or by telephone, as early as possible during development of the application but no later than 6 weeks before submission for prior approval. This requirement applies to a single grant application, whether a new, renewal, revision, or resubmission application, under any NIH support mechanism; it also applies to a group of applications, such as those for clinical trial networks, meeting the $500,000 threshold in the aggregate even if no single application in the group requests that much.

This policy does not apply to applications submitted in response to RFAs or other announcements that include specific budgetary limits. However, any such application must be responsive to budgetary limits specified or NIH will administratively withdraw the application and it will not be reviewed or considered for funding.

Applicants must seek agreement from IC staff at least six weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year (excluding consortium F&A costs). If staff is contacted less than six weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than $500,000, then approval should be sought even earlier.

The PD/PI must include a cover letter with the application identifying the PO contacted and the IC that has agreed to accept assignment of the application. CSR will accept such applications for review only if an IC has agreed to accept the application for consideration and the applicant submits with its application a letter to that effect with the name of the authorizing program staff member and IC affiliation (see The Peer Review Process). An application subject to this policy that does not include the required information in the cover letter will be administratively withdrawn and will not be reviewed or considered for funding.

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### 2.3.7.3 Resubmission of Unfunded RFA Applications

This policy applies to all activity codes that might be solicited via an RFA and to instances where there is a change in activity code. Unless otherwise noted in a particular FOA, unfunded applications should be submitted as **new** applications if the grant applications fall into the following categories:

1. Applications that were originally submitted in response to an RFA and now submitted as an investigator-initiated application.
2. Applications that were originally submitted as investigator-initiated applications and subsequently submitted in response to an RFA.
3. Applications that were originally submitted using one grant activity code and subsequently submitted using a different grant activity code (for example, an application that was originally an R01 and is now submitted as an R21).

The new application must be submitted on the scheduled due dates for new applications and follow all instructions that apply to new applications. Do not include an Introduction describing the changes and improvements made; do not mark text to indicate the changes; and do not explicitly address reviewers' comments. In these cases the reviewers will not be provided with the previous summary statement.

### 2.3.7.4 Submission of Resubmission Application

For original new applications (i.e., never submitted) and competing renewal applications, the NIH will accept only a single resubmission (A1) to the original application. If an applicant submits an A2 application for which only one resubmission is allowed, the A2 application will be administratively withdrawn by CSR and the principal investigator and applicant AOR will be notified. A resubmission must be submitted within 37 months of the original due date of the initial submission.

Applicants who do not receive funding after two submissions (i.e., the original and the single resubmission) may resubmit but only if the application is fundamentally changed to qualify as new.

A new application is expected to be substantially different in content and scope with more significant differences than are normally encountered in an amended application. A new application should include substantial changes in all sections of the Research Plan, particularly in the Specific Aims and the Research Strategy sections. There should be fundamental changes in the questions being asked and/or the outcomes examined. Changes to the Research Plan should produce a significant change in direction and approach for the research project. In the case of institutional Training and institutional Career Development applications, there must be a significant or substantial change in the programmatic, leadership, administrative, or other critical aspect of the program. Re-wording the title and/or Specific Aims or incorporating changes that are in response to comments in the previous summary statement does not constitute a substantial change in scope or content. Requests for review by a different review committee or funding consideration by a different NIH IC are not sufficient reasons to consider an application as new. Submission to a different FOA is also not sufficient to make an application new. (There are exceptions for applications following an RFA or changing activity code. See Resubmission of Unfunded RFA Applications above). The new application must be submitted on the scheduled due dates for new applications (see http://grants.nih.gov/grants/funding/submissionschedule.htm). It must not include an Introduction describing the changes and improvements made; and the text must not be marked to indicate the changes.

Applications are screened multiple times and checked to determine if the application is a new application, not simply another version of a project that has already received the maximum number of reviews. The

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first check is done within the Division of Receipt and Referral, CSR. Subsequent checks are performed by the SRO in charge of the review meeting and by IC program staff.

### 2.3.7.5 New Investigators and Early Stage Investigators

The NIH is committed to identifying and attracting new biomedical researchers and will continue to explore novel ways to encourage early transition to independence. NIH has implemented a number of policies specific to New Investigators, and in particular the category of New Investigator called Early Stage Investigator.

***New Investigator.*** In general, a PD/PI is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a significant NIH independent research award. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. See definitions section for additional information and references.

***Early Stage Investigator (ESI).*** An ESI is a New Investigator who is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent). Extensions of the end of ESI eligibility date may be requested following the procedures documented on the New Investigator Web site.

The NIH intends to support New Investigators at success rates comparable to those for established investigators submitting new applications. ESIs should comprise a majority of the New Investigators supported. Where possible, New Investigator applications will be clustered during review. The applications will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator.

NIH New Investigator policies are limited to applications for traditional research project grant (R01) support. Accordingly, the NIH strongly encourages New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding. To determine New Investigator and Early Stage Investigator status, NIH relies on the data entered by the individual in their eRA Commons Profile, therefore it is important that PD/PIs verify the accuracy of their personal profiles. Particularly key for ESIs are the terminal research degree and end date of residency data fields. ESI status and end of eligibility date also appear in the Commons profile for the individual.

### 2.3.7.6 Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance

The applicant organization is required to secure and retain a unique signature and dated assurance from the PD/PI for each submitted application, prior to submitting an application to the NIH. This assurance must be available to the NIH or other authorized DHHS or Federal officials upon request. Such an assurance must include at least the following certifications: 1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; 2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and 3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. If multiple PIs are proposed in an application, this assurance must be retained for all named PIs.

For individual Fellowship applications, this assurance requirement applies to the individual fellow and the sponsor. Such an assurance must include at least the follow certifications: (1) that the information submitted within the application is true, complete and accurate to the best of the Fellow's and Sponsor's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Fellow and

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Sponsor to criminal, civil, or administrative penalties; (3) that the Sponsor will provide appropriate training, adequate facilities, and supervision if a grant is awarded as a result of the application; (4) that the Fellow has read the Ruth L. Kirschstein National Research Service Award Payback and will abide by the Assurance if an award is made; and (5) that the award will not support residency training.

### 2.3.7.7 Post-Submission Grant Application Materials

Post-submission of application materials is not required. Adding materials to reviewer workload may be counterproductive, so applicants should carefully consider the need to send post-submission materials. For materials that are submitted after the initial grant application submission but prior to initial peer review, NIH will only accept such materials resulting from unforeseen administrative issues. This policy does not modify the Just-in-Time requirements or any other requests for additional information after the initial peer review.

For all research and research-related applications, individual fellowship, and individual career development awards, acceptable materials include:

- Revised budget page(s) (e.g., change in budget request due to a new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., change in senior/key personnel due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution (e.g., PD/PI moved to another university)
- News of an article accepted for publication (a copy of the article should not be sent)

All post-submission materials must conform to NIH policy on font size, margins, and paper size as referenced in the applicable application instructions. Any material using established forms/format pages (e.g. budget pages, biographical sketches) must follow standards for those pages. If post-submission material is not on a required form/format page, each explanation or letter is limited to one page. If the application has subprojects or cores, each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page.

Unacceptable post-submission materials include:

- Updated Specific Aims or Research Strategy pages
- Late-breaking research findings
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator

Exceptions to this policy include:

- Applications submitted in response to an RFA that has only one due date. Updated Specific Aims or Research Strategy pages, late-breaking research findings and new letters of support or collaboration will be allowed. If additional material is not required on a form/format page, post-submission materials for these applications are dependent on the number of pages of the Research Strategy section:
    - When the Research Strategy is fewer than 12 pages, additional materials are limited to one printed page.

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  - When the Research Strategy is limited to 12 pages, additional materials are limited to two printed pages.
  - When the Research Strategy is greater than 12 pages, additional materials are limited to three printed pages.
  - When the application has subprojects or cores, additional materials follow the page limit of the Research Strategy of each subproject or core as indicated above.
- Certain FOAs may allow specific other types of post-submission materials to facilitate the goals of the program. Such stipulations will be explained in the FOA.

For institutional training and training-related applications, including institutional Career Development Awards, up to three pages of post-submission materials will be allowed to present new information or data that was not available at the time of the application submission. Acceptable material includes:

- Updated information and data on the applicant pool, admissions, enrollment, appointments and/or achievements
- Updated faculty research support
- For training-related programs (e.g., R25) acceptable post-submission materials will be detailed in the FOA

For all types of applications, materials such as devices, videos, or other media that are considered essential to the review and generally are accepted by the IC for that type of application will be accepted at the discretion of the SRO managing the review.

Additional materials should be sent as a PDF attachment to an e-mail. E-mail communication is strongly encouraged whether the original application was submitted on paper or through Grants.gov. NIH recommends producing the documents electronically using text or word-processing software and then converting the document to PDF. This will allow the text to be searched electronically (i.e. do not scan files that have text as an image, scan as text file only). If e-mail is not feasible, send in a hard copy.

The materials must be submitted to the NIH SRO one month (30 calendar days) prior to the peer review meeting. Post submission materials will be not be accepted if fewer than 30 calendar days remain before the peer review meeting. The content of the additional materials may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or organizational officials. However, the communication to the SRO must include the concurrence of the AOR of the applicant institution; either the AOR should send the materials directly to the SRO, or the AOR may send their concurrence to the PD/PI who forwards the materials and the concurrence to the SRO. Materials sent without evidence of such concurrence will not be accepted. A communication from the PD/PI only or with a “cc” to the AOR will not be accepted.

The original application is kept intact. The SRO is responsible for uploading acceptable additional materials in the official electronic grant file. The PD/PI can check the application via the eRA Commons to see these materials in the section titled “Additions for Review”. This allows the information to be available to reviewers in a secure manner. Post-submission grant application materials used in the peer review process will be retained as part of the official grant file and remain part of the permanent record for that application.

The opportunity to submit additional materials should not be a means of circumventing submission deadlines, page limitations, or content requirements and should not substantially enhance, alter or add to the originally submitted application.

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After the initial peer review phase is completed, the Chief GMO of the IC is the NIH official responsible for accepting additional materials. Most of the material submitted after peer review can be submitted as part of the Just-in-Time process.

### 2.3.7.8 DUNS Number and CCR Registration Requirements

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual PD/PIs do not need to register for a DUNS.

Additionally, all applicant organizations must register in the Central Contractor Registry (CCR) and maintain the registration with current information at all times during which it has an application under consideration for funding by NIH and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. CCR is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR internet site at www.ccr.gov.

If an award is granted, the grantee organization must notify potential subrecipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

## 2.3.8 Application Forms

Exhibit 3 lists the required application forms for competing applications, which vary by support mechanism. These forms and associated instructions are available on the OER forms page (http://grants.nih.gov/grants/forms.htm).

**Exhibit 3. Required Forms for Competing Applications**

| Application Title | Form Number | Use |
|---|---|---|
| SF424 (R&R) Application Guide for NIH and Other PHS Agencies | **SF424 (R&R)** | The SF424 (R&R) form set, combined with PHS 398 components, is used for electronic submission. |
| SF424 (R&R) Individual Fellowship Application Guide for NIH and AHRQ | **SF424 (R&R)** and **PHS 416-1** | The SF424 (R&R) form set, combined with a PHS Fellowship Supplemental form component, is used for electronic submission of individual fellowship applications. The Fellowship Supplemental form component is from the PHS 416-1. |
| Application for a Public Health Service Grant | **PHS 398** | Form PHS 398 is used for paper submission for those programs that have not yet transitioned to electronic submission. |

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The majority of NIH competing applications now require electronic application submission. The FOA will identify whether the application requires electronic or paper submission. Paper submissions require use of the PHS 398 application form. An electronic submission requires the use of a unique set of application forms that combine SF424 (R&R) forms with agency-specific forms (e.g., 398 component forms, Fellowship supplemental component form). For electronically submitted applications, the applicable forms package and instructions is attached to a specific FOA. Questions about application forms and instructions may be directed to GrantsInfo, OER, NIH; see Part III for contact information.

## 2.3.9 Application Receipt Information and Deadlines

Applicants should carefully read instructions in the FOA and the application guide to determine submission requirements. The FOA will either provide unique application deadlines or refer to NIH's standard receipt dates.

NIH expects all applications (paper and electronic) to be submitted on time. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a cover letter explaining the reasons for the delay must be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Only DRR, CSR has the authority to accept a late application; however contacting DRR in advance will not influence the acceptance of a late application. The NIH policy on late applications is stated in the applicable application instructions.

### 2.3.9.1 Paper Applications

Paper application submission dates fall under two different categories: 1) Standard Postmark/Submission Dates (also known as "send by" dates) and 2) Special Receipt Dates (also known as "arrive by" dates) which are specified in RFAs and PAs.

Applications submitted for the standard submission dates are considered on time if they are sent on or before the appropriate date listed and a proof of mailing is provided. The critical determination is when the application is sent, not when it arrives at NIH. Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark, or a dated receipt from a commercial carrier or the USPS. Private metered postmarks are not acceptable.

All paper applications must be submitted via either courier delivery or the USPS. The number of copies specified in the application instructions or announcement must be submitted to the central NIH receipt point for CSR noted in Part III.

Preaddressed mailing address labels are available on the applicable forms page on the OER Web site.

Do not hand deliver your application to CSR. Applications delivered by individuals will not be accepted.

If the submission date falls on a weekend or a Federal holiday, the date for receipt/mailing is extended to the next business day. The application will be on time if it is sent on or before the following business day. The ten Federal holidays are: New Years Day, Birthday of Martin Luther King, Jr., Presidents Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

A paper application submitted in response to an FOA with a unique receipt date (if one is specified in the FOA) must be received at NIH by the specified date. However, an application received after the deadline may be accepted if it carries a legible proof-of-mailing date assigned by the carrier not later than 1 week prior to the deadline date. This applies only to FOAs with specific, published receipt dates, i.e., dates

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other than the standard ones used for investigator-initiated applications. For FOAs using the standard submission dates, the policies described above for "send by" dates apply.

### 2.3.9.2 Electronically Submitted Applications

For applications submitted electronically for the Standard Submission Dates, on time submission means the electronic grant application must be successfully submitted to Grants.gov on or before 5:00 p.m. local time (of the applicant institution/organization) on the appropriate date listed.

Applications submitted to FOAs with a single submission date are considered on time if they are submitted to Grants.gov on or before 5:00 p.m. local time (of the applicant institution/organization) on the appropriate date listed. Applications submitted for Special Receipt Dates are considered on time if they are submitted to Grants.gov on or before 5 p.m. local time on the Grants.gov Closing Date. RFAs and PARs with special receipt dates always must be received by Grants.gov on the dates designated in the announcement.

If a submission date falls on a weekend, it will be extended to the following Monday; any time the date falls on a Federal holiday (see list of Federal holidays in Paper Applications above), the submission date will be extended to the following business day. The application will be on time if it is submitted on or before the following business day.

- ***Regular Standard Submission/Receipt Dates.*** To be considered applications must be received at the NIH within two weeks of the standard submission date.

- ***Expedited Standard Submission/Receipt Dates.*** To be considered applications must be received at the NIH within one week of the standard submission date.

- NIH will not consider late applications for the Special Receipt Dates for RFAs and PARs.

- NIH does not expect to accept any applications received beyond the window of consideration.

The windows of time for consideration of late applications have been carefully chosen so that the late applications can be processed with the cohort of on-time applications. Note that the late window always ends in a receipt (not submission) date.

Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH in advance will not influence the acceptance of a late application. Additional information on submission of electronic applications can be found in the applicable SF424 (R&R) Application Guide.

### 2.3.9.3 Modified Submission Policy for Appointed Members of NIH Review and Advisory Group and Reviewers with Recent Substantial Service

An alternative submission policy is available for certain applications submitted listing as PD/PI individuals serving as appointed members of NIH chartered standing study sections, NIH Boards of Scientific Counselors, NIH Advisory Boards or Councils, NIH Program Advisory Committees, and/or peer reviewers who have served as regular or temporary members six times in 18 months. This policy applies to R01, R21, and R34 applications that would normally be received on standard application submission dates (not special receipt dates); and allows for applications to be submitted as soon as they are fully developed. The applications will be reviewed no later than 120 days after receipt. Applications using the multiple PD/PI model, are eligible if one or more of the PD/PIs are eligible for continuous

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submission. Continuous submission does not apply to applications for which the eligible members have roles other than PD/PI, including eligible members as sponsors for fellowships and mentors for career award applications.

See frequently asked questions at http://cms.csr.nih.gov/ResourcesforApplicants/ContinuousSubmissionFAQ.htm.

### 2.3.10 Fraud, Waste and Abuse of NIH Grant Funds

Any individual who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to NIH grants or grant funds should consider contacting:

- Your institution's Office of Sponsored Research, Compliance Office, or other responsible office,
- The NIH CGMO listed in the NoA for the IC that funded the grant,
- The DGCO/OPERA/OER.

In addition, allegations of criminal offenses should be reported to the Department of Health and Human Services, OIG Hotline.

The OIG has authority within HHS to conduct criminal investigations. The HHS OIG maintains a post office box and a toll-free hotline for receiving information from individuals concerning fraud, waste, or abuse under HHS grants and cooperative agreements. The identity of the caller is kept confidential, and callers are not required to give their names. The address and telephone number of the OIG and the OIG hotline are included in Part III.

Further allegations of non-criminal misuse of grant funds, and grantee conflict of interest should be reported to the NIH OMA.

OMA provides a centralized management survey and review capability to promote program integrity, conducts appraisals of alleged incidents of waste, fraud, and abuse and has lead responsibility for cases received through the Office of Inspector General (OIG) Hotline that are referred to NIH for action. OMA has no authority to undertake criminal investigations. OMA refers all allegations of criminal offenses to the OIG for investigation. The address and telephone number for the OMA, DPI are included in Part III.

Examples of fraud, waste, and abuse that should be reported include, but are not limited to, embezzlement, misuse, or misappropriation of grant funds or property, and false statements, whether by organizations or individuals. Other examples include theft of grant funds for personal use; using funds for non-grant-related purposes; theft of federally owned property or property acquired or leased under a grant; charging the Federal government for the services of "ghost" individuals; charging inflated building rental fees for a building owned by the grantee; submitting false financial reports; and submitting false financial data in bids submitted to the grantee (for eventual payment under the grant).

The Federal government may pursue administrative, civil, or criminal action under a variety of statutes relating to fraud and making false statement or claims. Part II includes administrative and other remedies the Federal government may use if a grantee deliberately withholds information or submits fraudulent information or does not comply with applicable requirements. Even if a grant is not awarded, the applicant may be subject to penalties if the information contained in or submitted as part of an application, including its certifications and assurances, is found to be false, fictitious, or fraudulent.

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The Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 et seq., provides for the administrative imposition by HHS of civil penalties and assessments against any person who knowingly makes false, fictitious, or fraudulent claims to the Federal government for money, including money representing grants, loans, or benefits. A civil penalty of not more than $5,500 may be assessed for each such claim. If a grant is awarded and payment is made on a false or fraudulent claim, an assessment of not more than twice the amount of the claim, up to $150,000, may be made in lieu of damages. Regulations established by HHS at 45 CFR part 79 specify the review process for imposing civil penalties and assessments, including hearing and appeal rights.

The Criminal False Claims Act, 18 U.S.C. 287, and 18 U.S.C. 1001, provides for criminal prosecution of a person who knowingly makes or presents any false, fictitious, or fraudulent statements or representations or claims against the United States. Violations of these statutes carry a maximum sentence of 5 and 8 years imprisonment, respectively.

The Civil False Claims Act, 31 U.S.C. 3729(a), provides for imposition of penalties and damages by the United States, through civil litigation, against any person who knowingly makes a false or fraudulent claim for payment, makes or uses a false record or false statement to get a false claim paid or approved, or conspires to defraud the Federal government to get a false claim paid. A "claim" includes any request or demand for money or property made to the United States or to a contractor, grantee, or other recipient, if the Federal government provides or will reimburse any portion of the funds claimed. Civil penalties of $5,500 to $11,000 may be imposed for each false claim, plus damages of up to three times the amount of the damages the government sustains because of the violation, and the costs of any civil action brought to recover such penalties and damages.

NIH also may administratively recover misspent grant funds pursuant to the authorities contained in 45 CFR parts 74 and 92.

## 2.3.11 Availability and Confidentiality of Information

### 2.3.11.1 Availability of Information

Except for certain types of information that may be considered proprietary or private information that cannot be released, most grant-related information submitted to NIH by the applicant or grantee in the application or in the post-award phase is considered public information and, once an award is made, is subject to possible release to individuals or organizations outside NIH. The statutes and policies that require this information to be made public are intended to foster an open system of government and accountability for governmental programs and expenditures and, in the case of research, to provide information about federally funded activities.

NIH routinely places information about awarded grants, including project title, the name of the PD/PI, and the project description, on the RePORT Web site (see http://report.nih.gov). For funded research grant applications, NIH also sends the project description provided by an applicant to the DoC's NTIS. NTIS disseminates scientific information for classification and program analysis. The public may obtain the project descriptions from RePORT or request them from NTIS. Other information may be released case by case as described in this subsection.

Several policies require acknowledgment of support and a disclaimer for publications, inventions, and other research products, as provided in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources and elsewhere in the NIHGPS.

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### 2.3.11.2 Confidentiality of Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets, information that is commercial or financial, or information that is privileged or confidential, the pages containing that information should be identified as specified in the application instructions.

When such information is included in the application, it is furnished to the Federal government in confidence, with the understanding that the information will be used or disclosed only for evaluation of the application. The information contained in an application will be protected by NIH from unauthorized disclosure, consistent with the need for peer review of the application and the requirements of the FOI and Privacy Acts (discussed below). However, if a grant is awarded as a result of or in connection with an application, the Federal government has the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Federal government's right to use the information if it is obtained without restriction from another source.

#### 2.3.11.2.1 Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a (as amended), and its implementing regulations (45 CFR part 5b) provide certain safeguards for information about individuals maintained in a system of records (i.e., information may be retrieved by the individual's name or other identifying information). These safeguards include the rights of individuals to know what information about them is maintained in Federal agencies' files (hard copy or electronic) and how it is used, how they may obtain access to their records, and how to correct, amend, or request deletion of information in their records that is factually incorrect.

Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act. The NIH Privacy Act Systems of Records that covers NIH grant records is:

- 09-25-0036, Extramural Awards and Chartered Advisory Committees: (IMPAC 2), Contract Information (DCIS), and Cooperative Agreements Information

This system of record provides guidance on requirements for the management of applicable grant records in NIH's possession and include appropriate routine uses of such information. It also includes requirements for safeguarding the records and for record retention and disposal.

Parties other than PD/PIs may request the release of Privacy Act grant records. Such requests are processed under FOIA. For example, information requested by co-investigators in grant applications is released to them only when required under FOIA because they have no right of access under the Privacy Act. When releasing information about an individual to a party other than the subject of the file, NIH will balance the individual's right to privacy with the public's right to know as provided by the FOIA.

Records maintained by grantees ordinarily are not subject to the requirements of 45 CFR part 5b.

#### 2.3.11.2.2 The Freedom of Information Act

The Freedom of Information Act, 5 U.S.C. 552, and implementing HHS regulations (45 CFR part 5) require NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information. These policies and regulations apply to information in the possession of NIH. Generally NIH cannot require grantees or contractors under grants to permit public access to their records. An exception related to certain research data is described in this subsection.

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NIH generally will release the following types of records pursuant to a FOIA request:

- Funded applications and funded progress reports, including award data.
- Final reports that have been transmitted to the grantee organization of any audit, survey, review, or evaluation of grantee performance.

NIH generally will withhold the following types of records or information in response to a FOIA request:

- Pending competing grant applications
- Unfunded new, renewal, and revision applications
- Financial information pertaining to project personnel, such as institutional base salary information
- Information pertaining to an individual, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
- Predecisional opinions in interagency or intraagency memorandums or letters expressed by Federal government officers, employees, or consultants
- Evaluative portions of site visit reports and peer review summary statements, including impact/priority scores
- Trade secrets and commercial, financial, and otherwise intrinsically valuable items of information that are obtained from a person or organization and are privileged or confidential
- Information which, if released, would adversely affect the competitive position of the person or organization
- Patent or other valuable commercial rights of the person or organization.

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If, after receiving a FOIA request, NIH has substantial reason to believe that information in its records could reasonably be considered exempt from release, the appropriate NIH FOI office will notify the applicant or grantee, through the PD/PI, before the information is released. In the case of multiple PD/PI's the contact PD/PI will be notified and is responsible for coordinating any response to the notice. Multiple submissions will not be accepted. The PD/PI will be given five (5) working days to identify potentially patentable or commercially valuable information that the PD/PI believes should not be disclosed. Any such submission must be specific as to the nature and type of commercial harm that will result if the requested information is released. Submissions that merely state in general terms that the grant application or portions should not be released will not be honored. If the PD/PI does not respond within that time period, the grant will be prepared for release in accordance with applicable FOIA policies and released to the requester. If the PD/PI does identify commercial or proprietary information an NIH official will review that response. After NIH consideration of the response, the PD/PI and grantee will be informed if NIH does not agree with the PD/PI's position. If a document contains both disclosable and non-disclosable information, the non-disclosable information will be redacted and the balance of the document will be disclosed.

The HHS regulations implementing FOIA provide that only the NIH FOI Officer may deny requests for information. Requests for information, the release of which is believed to be exempt under FOIA, are

referred to the NIH FOI Officer along with written documentation of the rationale for nondisclosure. If the NIH FOI Officer determines that the requested information is exempt from release under FOIA, the requester may appeal that determination to the Deputy Assistant Secretary for Public Affairs (Media), HHS. Additional information on the FOIA process is available at the NIH FOI Office Web site (http://www.nih.gov/icd/od/foia).

#### 2.3.11.2.3 Access to Research Data

NIH handles requests for the release of research data by certain types of recipients as FOIA requests. The term "research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

As required by 45 CFR part 74.36, grantees that are institutions of higher education, hospitals, or non-profit organizations must release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). If the data are publicly available, NIH directs the requester to the public source. Otherwise, the IC FOI coordinator handles the request, consulting with the affected grantee and the PD/PI. This requirement also provides for assessment of a reasonable fee to cover grantee costs and (separately) the NIH costs of responding.

This requirement to release research data does not apply to commercial organizations or to research data produced by State or local governments. However, if a State or local governmental grantee contracts with an educational institution, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to the disclosure requirement.

Additional information is available on the NIH Web site at http://grants.nih.gov/grants/policy/data_sharing/index.htm. (Also see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.)

### 2.3.12 Protecting Sensitive Data and Information Used in Research

Recipients of NIH funds are reminded of their vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known and is satisfactory to the transmitter. See also Public Policy Requirements and Objectives—Federal Information Security Management Act.

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# 2.4 THE PEER REVIEW PROCESS

Competing applications for NIH grants and cooperative agreements, including those renewals and revisions, are subject to peer review as required by sections 406 and 492 of the PHS Act, the NIH Reform Act of 2006, or by NIH policy. NIH policy is intended to ensure that applications for funding submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias. The peer review system used by NIH, often referred to as the "dual review system," is based on two sequential levels of review for each application—initial review by an IRG or SRG, and a second level of review by the IC National Advisory Council/Board.

The NIH peer review process has evolved over the years to accommodate changes in workload, resource constraints, and recommendations of various groups that have studied it. However, the underlying basis for the system—to provide a fair and objective review process in the overall interest of science—has not changed. Information concerning NIH's peer review process may be found at http://grants.nih.gov/grants/peer/peer.htm. Information also is available from GrantsInfo, or from OEP (see Part III).

## 2.4.1 Initial Review

### 2.4.1.1 Responsibilities

The DRR in the CSR is the receipt point for all competing grant applications submitted to NIH, whether the peer review will be conducted by CSR or by an IC. The primary determining factors in whether CSR or an IC will be responsible for the peer review are the announcement type, the support mechanism, and/or the program. In general, CSR is responsible for the initial review of research project grant applications (including AREA applications), Kirschstein-NRSA individual fellowship applications, and SBIR/STTR applications, while the ICs handle the initial review of conference grant applications, applications resulting from RFAs, and program project and center grant applications.

CSR also may review other types of applications at IC request. When the IC is responsible for the initial review, CSR reviews the application for completeness, and the scientific review office of the soliciting IC reviews the application for responsiveness to the RFA, coordinates the initial technical review, and prepares the summary statements.

CSR Referral Officers, who are senior health science administrators with both research and scientific review experience, assign each application to one or more ICs for potential funding and to an IRG or SRG for initial review of the scientific merit of the application. These determinations are made on the basis of the application's contents, the referral guidelines, and any written request by the applicant organization (accompanying the application) for a specific study section or IC assignment.

SRGs, including CSR study sections, are organized by scientific discipline or current research areas and are managed by health scientist administrators functioning as SROs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRO often adds temporary members or other additional reviewers. Ad hoc SEPs are formed to review applications that cannot be reviewed by a standing review group or study section because they require special expertise or involve other special circumstances.

SRGs, whether study sections or SEPs, are primarily composed of non-federal scientists who have expertise in relevant scientific disciplines and are actively engaged in research. NIH's conflict-of-interest and confidentiality of information requirements for reviewers are intended to promote an unbiased review

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process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Applicants are notified by e-mail that the application has been received and that they may have access to the SRO, SRG, and IC assignments for the application in the eRA Commons. At this time, applicants may request reconsideration of the SRG and IC assignment. Applicants also are notified by e-mail to check eRA Commons for any change in the application's SRG or IC assignment, as well as a change in Council date. Once the assignment process is completed, the SRO is the contact for all communication with the applicant until the conclusion of the SRG meeting. An applicant organization may withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PD/PI and an AOR.

In preparation for the initial review, SROs review applications to determine whether they are complete and conform to administrative requirements. For each reviewable application, they then assign (from among the standing and temporary members) at least two reviewers to write a critique of the application and at least one reader (discussants) to be prepared to discuss the application in detail.

Following the initial review, the SRO generally prepares a summary statement for most applications reviewed. The summary statement includes the reviewers' written comments, and, for scored applications, a summary of strengths and weaknesses, other summary highlights of the discussion, and a impact/priority score. Summary statements are then provided to the IC's program staff and the PD/PI.

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### 2.4.1.2 Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five scored review criteria, and additional review criteria (as applicable for the project proposed). All of the criteria, weighted as appropriate for each application or as described in the FOA, will be considered when assigning the overall impact score.

### 2.4.1.3 Scored Review Criteria

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, and enhance health. For research grant applications, and most other types of applications, reviewers judge the overall impact to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, taking into account, among other pertinent factors: Significance, Investigator(s), Innovation, Approach, and Environment. These scored review criteria may not be applicable for some types of applications. When these criteria are not applicable, the FOA will include the specific review criteria.

Reviewers will consider each of the five criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- ***Significance.*** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the application are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- ***Investigator(s).*** Are the PD/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- ***Innovation.*** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- ***Approach.*** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- ***Environment.*** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

#### 2.4.1.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- ***Protections for Human Subjects.*** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

  For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

- ***Inclusion of Women, Minorities, and Children.*** When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

- ***Vertebrate Animals.*** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of

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animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

- ***Resubmission Applications.*** When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

- ***Renewal Applications.*** When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

- ***Revision Applications.*** When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

- ***Biohazards.*** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

### 2.4.1.5 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- ***Budget and Period Support.*** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

- ***Select Agent Research.*** Reviewers will assess the information provided in this section of the application, including 1) the select agent(s) to be used in the proposed research, 2) the registration status of all entities where select agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of select agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the select agent(s).

- ***Applications from Foreign Organizations.*** Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

- ***Resource Sharing Plans.*** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome-Wide Association Studies (GWAS).

Although the review criteria are intended for use primarily with investigator-initiated research project grant applications (e.g., R01 and P01), including those in response to PAs, to the extent reasonable, the

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criteria also will form the basis of the review of solicited applications and non-research activities. However, for some activities (e.g., construction grants), the use of these criteria may not be feasible. Applications also may be reviewed against other pertinent factors as stated in RFAs or PAs.

### 2.4.2 Appeals of Initial Scientific Review

To preserve and underscore the fairness of the NIH peer review process, NIH has established a peer review appeal system to provide applicants the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was procedurally flawed. This appeal process is not intended to consider differences of scientific opinion between or among PD/PIs and reviewers.

The applicant should discuss concerns about the conduct of the review, whether the initial review was conducted by CSR or by the IC, with the PO responsible for the application; the PO will attempt to resolve the applicant's concerns. If, after discussion with the PO, the applicant still has concerns, the AOR may submit a formal letter of appeal to the PO, who will handle it in accordance with the appeal procedures outlined below.

The PO will consult with the SRO or staff of the IC scientific review office. This consultation may result in a decision to re-review the application. A re-review consists of a review of the same application, not a revised version, by the same or another review group without access to the summary statement of the disputed review. If the NIH staff and the PD/PI cannot agree on a course of action, the appeal will be reviewed by the designated IC Appeals Officer. That official will make the appeal letter available to the Council along with the IC recommendation on the appeal and any written comments from the SRO or review group. The Council may reject the appeal and let the initial review results stand or recommend that the application be re-reviewed. The Council's decision may not be further appealed.

### 2.4.3 National Advisory Council or Board Review

Summary statements for those applications recommended for further consideration are presented to the assigned IC National Advisory Council or Board (hereafter "Council") for use in the second level of review. Council members include senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission. The Council reviews applications not only for scientific and technical merit, as judged by the SRG, but also for relevance to the IC's programs and priorities. The Council may concur with the SRG's recommendation, may decide not to recommend an application on the basis of program or policy considerations, or may recommend deferral of an application and refer it back to the SRG for re-review. With very limited exception, an application may not be considered for funding unless it has received a favorable recommendation by both the SRG and the Council. For some applications (e.g., Kirschstein NRSA Fellowship applications) the second level of review is conducted by senior level IC staff.

### 2.4.4 Disposition of Applications

All incomplete applications, non-compliant modular applications, and applications determined to be nonresponsive to FOA requirements will not be reviewed. If the FOA remains open with subsequent submission dates, the applicant may resubmit a corrected or complete version of an investigator-initiated application for consideration in the next review cycle.

Following the initial review, the summary statement will be available to the PD/PI in the eRA Commons. The IC Director or designee is the official who has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an

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application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit one revised version of the application for review in a future cycle.

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The process leading to an award, including the business management review performed by the GMO, is described in Completing the Pre-Award Process below. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any NIH or HHS official or board.

## 2.5 COMPLETING THE PRE-AWARD PROCESS

Following the peer review process, applications that an IC may fund are reviewed for a number of other considerations. These include, as applicable, alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements. The applicant may be asked to submit additional information (such as other support or verification of IACUC review) or to undertake certain activities (such as negotiation of an F&A cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before NIH makes a new award, grantees must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support. The pre-award process for non-competing continuation awards is a streamlined version of this process, including an assessment of progress (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

### 2.5.1 Just-in-Time Procedures

NIH uses Just-in-Time procedures for certain programs and award mechanisms (each FOA will include specific guidance on the use). These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

Applicants will be notified (primarily by e-mail) when Just-in-Time information is needed. This notification is not a notice of award nor should it be construed to be an indicator of possible funding. Applicants should only submit this information when requested. Information can be submitted electronically using the Just-in-Time feature in the eRA Commons. Other types of submission directly to the assigned grants specialist (e-mail, fax, hard copy mail) are also acceptable as long as it is clear the submitter is an AOR. In some circumstances the GMO may ask for information in addition to the descriptions below, e.g., if the application involves hESCs and the applicant did not identified a hESC from the NIH Registry in the application.

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The requirement for applicants to verify the accuracy and validity of all administrative, fiscal, and programmatic information extends to information submitted through the Just-in-Time process. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award. This includes items such as Other Support changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any Senior/Key Personnel; or any changes in the use or approval of vertebrate animals or human subjects. Similar to the NIH public policy requirements, applicants are responsible for establishing and maintaining the necessary processes to monitor its compliance and informing NIH of any problems or concerns. Failure to address changes to Just-in-Time submissions prior to award does not diminish the applicant's responsibility to address changes post-award by submitting a prior approval request to NIH in accord with Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award.

***Other Support.*** Information on other support will be requested as part of the Just-in-Time procedures. Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes or gifts are not included. Other support is requested for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Information on Other Support is not specifically requested for Program Directors, training faculty, and other individuals involved in the oversight of training grants since applicable information is collected in other sections of a training grant application. It is also not requested for individuals categorized as Other Significant Contributors.

IC scientific program and grants management staff will review this information before award to ensure the following:

- Sufficient levels of effort are committed to the project.
- There is no scientific, budgetary, or commitment overlap.
    - Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.
    - Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.
    - Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application.
    - Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the IC with the applicant and the PD/PI at the time of award.
- Only funds necessary to the approved project are included in the award.

***Certification of IRB Approval.*** If the proposed project involves human subjects research, the certification date of IRB review and approval must be submitted. Pending or out-of-date approvals are not acceptable. *See Public Policy Requirements/Human Subjects for additional information*.

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***Verification of IACUC Approval.*** If the proposed project involves research including live vertebrate animals, the verification date of IACUC approval along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable. *See Public Policy Requirements/Animal Welfare for additional information.*

***Human Subjects Education Requirement.*** If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted. *See Public Policy Requirements/Human Subjects/Education in the Protection of Human Research Participants for additional information.*

***Human Embryonic Stem Cells (hESCs).*** If the proposed project involves hESCs and the applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line(s) should be included in the Just-in-Time submission.

***Other Information Requested by the Awarding IC.*** NIH IC's may also request additional Just-in-Time information on a case-by-case basis, such as revised budgets or changes to the human subjects or vertebrate animal sections of the application.

## 2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement

When requested by NIH as part of the pre-award process, PD/PIs and the AOR should discuss potential changes in scope with NIH PO and revise the Project Summary/Abstract, Specific Aims, and/or Public Health Relevance sections of their application as appropriate. Once all issues are resolved, applicants should e-mail a document with final versions of the revised sections to the IC-designated e-mail address (normally a Program Official, Grants Management Official, or centralized e-mail box) as a single Microsoft Word or PDF file. Be reminded that all revised application information submitted to the NIH must be approved by an AOR. Applicants should use the template found at: http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_ModifiedScopeTemplate.doc. The template includes specific headings that must be used for each section. All three headings must be included in the document that is submitted even if a particular section had no changes from the previous submission. If there are no changes for a section include the header but leave the text area blank to ensure appropriate processing of this information by NIH's electronic systems.

## 2.5.3 Determining Applicant Organization Eligibility

All applicant organizations must complete the one-time eRA Commons registration process prior to submitting any application (paper or electronic) to the NIH. During the registration process, NIH may make a preliminary assessment of applicant organization eligibility. Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH reserves the right to deny registration if an organization is determined not to be an appropriate applicant for a particular FOA.

NIH awards may be made only to eligible applicants. Continued funding is dependent on the grantee's continued eligibility. In general, domestic or foreign, public or private, non-profit or for-profit organizations and individuals are eligible to receive NIH grants. However, on the basis of statutory, regulatory, or published policy limitations, under certain programs or types of awards, NIH may limit eligibility to, or exclude from eligibility, classes or types of entities. Examples are limitations on the participation of foreign entities, and programs under which only small businesses are eligible applicants. The determination of eligibility includes verification of the applicant's status. The applicant may be

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required to provide proof of its status by submitting documentation; otherwise the AOR's signature on the application certifies that the applicant is eligible to apply for and receive an award (e.g., a small business applying under the SBIR or STTR programs).

In addition to reviewing organizational eligibility, NIH may consider other factors relating to the applicant's ability to responsibly handle and account for Federal funds and to carry out the project. These factors include the applicant's intended role in the project, the location where the project will be performed, the role of the PD/PI in the project, and the PD/PI's employment and citizenship status. Although some of these same considerations are reviewed as part of the peer review, NIH's concern at this stage in the process is making an award to a legal entity that will be accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. NIH will not make an award to an applicant that does not have a substantive role in the project and would simply serve as a conduit for another entity.

## 2.5.4 Determining Eligibility of Individuals

It is the responsibility of the applicant organization to select the individuals who have the appropriate expertise to manage the scientific and administrative aspects of the project. The eligibility of these individuals to complete the project will be evaluated during peer review and at the IC level by grants management and program staff.

The GMO will verify whether the proposed PD/PI or other senior/key personnel are debarred or suspended from participation in Federal assistance programs (see Public Policy Requirements and Objectives—Debarment and Suspension for certification requirements).

Generally, PD/PIs and other personnel supported by NIH research grants are not required to hold any particular education degree, and are not required to be U.S. citizens. However, some NIH programs/mechanisms have a citizenship requirement. Any citizenship requirement will be stated in the FOA. In these cases, individuals are required to have the appropriate citizenship status when the award is made rather than when the application is submitted. For example, under most career development awards or Kirschstein-NRSA individual fellowships, the individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence at the time of award.

NIH requires the applicant to determine that individuals' visas will allow them to remain in this country long enough for them to be productive on the research project, but NIH does not provide guidance on or assess the different types of visas. NIH expects grantee organizations to have policies, consistently applied regardless of the source of funds, to address this area. If a grant is awarded and an individual's visa will not allow a long enough stay to be productive on the project, NIH may terminate the grant (see Administrative Requirements—Changes in Project and Budget and Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support).

The eligibility requirements for trainees and additional eligibility requirements for fellows are addressed in Ruth L. Kirschstein National Research Service Awards chapter in IIB.

In the post-award phase, NIH monitors changes in grantee and project status to ensure they meet legal and programmatic requirements and takes actions necessary to protect the Federal government's interests.

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## 2.5.5 Cost Analysis and Assessment of Management Systems

The GMO will ensure that a cost analysis is performed on any application that requires a detailed budget. Cost analysis involves obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining data to determine the necessity for, and the reasonableness and allowability of, the costs included in the application budget. The extent of cost analysis will depend on the type of funding instrument and award mechanism, the complexity of the project, prior experience with the applicant, and other factors. Information on the applicable cost principles and on allowable and unallowable costs under NIH grants is provided in the Cost Considerations chapter.

The amount of NIH funding is based on reasonable and allowable costs consistent with the principles of sound cost management, considering IC priorities (e.g., program relevance), constraints on the growth of average grant costs, and available funds.

In addition to considering the specific information provided in the application, the GMO determines the adequacy of the applicant's financial and business management systems that will support the expenditure of and accountability for NIH funds. When an applicant has had no prior Federal grants or cost-reimbursement contracts, the GMO may review the applicant's financial management and other management systems before award, or within a reasonable time after award, to determine their adequacy and acceptability. For an applicant with prior NIH or other Federal cost-reimbursement awards, the GMO may review recent audit reports and other available information to determine whether the applicant's management systems meet the standards established in 45 CFR part 74 or 45 CFR part 92, as appropriate. The GMO will advise the applicant if additional information is required. On the basis of the review results, the GMO will determine the need for any corrective action and may impose special conditions on the award.

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# Part II: Terms and Conditions of NIH Grant Awards

## Subpart A: General

## 3 OVERVIEW OF TERMS AND CONDITIONS

Part II includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards. Subpart A (IIA) includes those terms and conditions that apply, in general, to NIH awards. Subpart B (IIB) either expands on IIA coverage or specifies additional or alternate terms and conditions for particular types of awards, recipients, or activities.

These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

NIH grants awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in the NoA
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts. This also includes any recent legislation.
- 45 CFR part 74 or 45 CFR part 92, as applicable.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIHGPS generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the GMO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIHGPS apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the NIHGPS.

This NIHGPS is an aid to the interpretation of statutory and regulatory requirements. These terms and conditions are intended to be compliant with governing statutes and the requirements of 45 CFR parts 74 and 92, as modified by previously approved waivers and deviations. However, in the case of a conflict, the statutes and regulations govern.

If there is a perceived conflict between or among these three categories of requirements—statutory and regulatory requirements, the terms and conditions in the NIHGPS, and award-specific terms and

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conditions—or if the grantee has other questions concerning award terms and conditions, the grantee should request written clarification from the GMO. This may be done at any time; however, if the inclusion of the term or condition would cause the grantee not to accept the award or to be unable to comply, the question should be raised before funds are requested from the HHS payment system. By drawing funds from the HHS payment system, the grantee agrees to the terms and conditions of the award.

## 3.1 FEDERALWIDE STANDARD TERMS AND CONDITIONS FOR RESEARCH GRANTS

In order to create greater consistency in the administration of Federal research awards, all Federal research agencies now utilize a standard core set of administrative terms and conditions on research and research-related awards that are subject to OMB Circular A-110 (2 CFR part 215), to the extent practicable. The Government-wide core set of administrative requirements and other pertinent documents are posted at: http://www.nsf.gov/bfa/dias/policy/rtc/index.jsp. Grantees are encouraged to review the companion documents which include a Prior Approval Matrix, National Policy Requirement Matrix, Subaward Requirement Matrix, and Agency-Specific Requirements. NIH implementation of these Federalwide research terms and conditions has no significant change in the requirements or terms and conditions for NIH awardees.

## 3.2 NIH STANDARD TERMS OF AWARD

Federal administrative requirements allow agencies to waive certain cost-related and administrative prior approval; these are known as expanded authorities. In 2001, NIH extended these authorities to all NIH awards except for the provision to automatically carry over unobligated balances; therefore the term "expanded authorities" has been replaced with "NIH Standard Terms of Award". See Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award for more details.

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# 4 PUBLIC POLICY REQUIREMENTS, OBJECTIVES AND OTHER APPROPRIATION MANDATES

NIH grants are subject to requirements intended to ensure that recipient organizations handle their Federal awards responsibly. Grantees are required to adopt and enforce policies that minimize the opportunity for improper financial gain on the part of the organization, its employees, and organizations and individuals whom they may collaborate, and that limit the potential for research results to be tainted by possible financial or other gain. In addition, NIH grantees are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.

This chapter addresses public policy requirements, objectives, and other appropriation mandates applicable to NIH awards. The term "public policy" indicates that the requirement is based on social, economic, or other objectives or considerations that may be attached to the expenditure of Federal funds by grantees, consortium participants, and contractors, in general, or may relate to the expenditure of Federal funds for research or other specified activities.

In addition to cross-cutting requirements that some or all Federal agencies must apply to their grant programs, NIH grantees are subject to requirements contained in the HHS annual appropriations act that apply to the use of NIH grant funds, applicable provisions in other Federal agencies' appropriations acts, including Treasury, and other Federal statutes. Some of those requirements are included here in a separate section titled Appropriation Mandates since they have been included in the appropriations acts for several years with little or no change. Those requirements may be changed or other requirements may be added in the future.

The public policy requirements, objectives, and appropriation mandates listed in Exhibit 4 apply to all NIH awards with exceptions as noted.

## 4.1 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its grantees. The public policy requirements specified in this section set many of those standards. The signature of the AOR on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions. The policies, certifications and assurances listed in this section may or may not be applicable to the project, program, or type of applicant organization. Requirements/objectives are listed in alphabetical order.

As noted in this section, some requirements may necessitate the submission of a separate document (e.g., human subjects assurance, IRB certification, civil rights assurance). Applicants and grantees should take particular note of these requirements (for example, see specific sections on Human Subjects Protections and Civil Rights Protections), the absence or inadequacy of which may delay an award or render an applicant ineligible for award.

The grantee is responsible for: 1) establishing and maintaining the necessary processes to monitor its compliance and that of its employees, consortium participants, and contractors with these requirements; 2) taking appropriate action to meet the stated objectives; and, 3) informing NIH of any problems or concerns.

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If a grant is awarded on the basis of false or misrepresented information, or if a grantee does not comply with these public policy requirements, NIH may take any necessary and appropriate action, including using any of the remedies described in Administrative Requirements—Enforcement Actions or other available legal remedies.

Exhibit 4 contains information to help the grantee determine what public policy requirements, objectives and appropriations mandates apply to its activities and whether a requirement should be included in a consortium agreement or a contract for routine goods or services under the grant (see Glossary in Part I for definitions). The exhibit distinguishes between these types of transactions under a grant and indicates (by "Y" for Yes or "NA" for Not Applicable) whether a given requirement normally would apply. However, even if the exhibit indicates that a requirement is not applicable that requirement potentially could be applicable in a specific situation, e.g., if a contract under a grant involves research activity. Therefore, this exhibit should be used as general guidance only. The grantee should consult the terms and conditions of its award and should contact the GMO if it has any question concerning the applicability of a particular public policy requirement or objective.

Exhibit 4 also indicates where, in the NIHGPS, the individual public policy requirements, objectives and appropriation mandates are covered in more detail. The grantee should also consult its attorney, as appropriate, regarding particular questions about the governing statute or regulation as applied to its specific circumstances. Other cited policies or documents may provide additional information.

In addition to the requirements addressed in this section, there are applicable NIH administrative requirements outlined in the Administrative Requirements chapter.

Some programs may have special requirements and are covered in IIB.

**Exhibit 4. Public Policy Requirements, Objectives and Appropriation Mandates ***

| Requirement, Objective, or Appropriation Mandate | Grantee | Subaward/ Consortium Participant | Contractor under Grant (routine goods/services) |
|---|---|---|---|
| Acknowledgment of Federal Funding (Appropriation Mandate) 4.2.1 | Y | Y | NA |
| Age Discrimination Act of 1975 4.1.2.4 | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) |
| Animal Welfare 4.1.1 | Y | Y | Y |
| Architectural Barriers Act of 1968 10.10 | Y (Construction grants and any grant involving major A&R) | Y | Y |
| Certificates of Confidentiality 4.1.4.1 | Y | Y | Y |

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| Requirement, Objective, or Appropriation Mandate | Grantee | Subaward/ Consortium Participant | Contractor under Grant (routine goods/services) |
|---|---|---|---|
| Certification of Filing and Payment of Taxes (Appropriation Mandate) 4.2.2 | Y | NA | NA |
| Civil Rights Act of 1964 (Title VI) 4.1.2.1 | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) |
| Clean Air and Clean Water Act 10.10 | Y (Construction grants only); for contracts exceeding $100,000 | Y | Y |
| Clinical Trials.gov 4.1.3 | Y | Y | NA |
| Coastal Zone Management Act of 1972 10.10 | Y (Construction grants only) | Y | Y |
| Confidentiality of Alcohol and Drug Abuse Patient/Client Records 4.1.4.2 | Y | Y | Y |
| Conservation of Petroleum and Natural Gas (EO 12185) 10.10 | Y (Construction grants only) | Y | Y |
| Controlled Substances 4.1.5 | Y | Y | Y |
| Copeland Act, when required by statute 10.10 | Y (Construction grants only) | Y | Y |
| Data and Safety Monitoring 4.1.15.6 | Y | Y | Y |
| Davis-Bacon Act, when required by statute 10.10 | Y (Construction grants only) | Y | Y |
| Debarment and Suspension 4.1.6 | Y (NA to certain foreign organizations) | Y (NA to certain foreign organizations) | Y If contract equals or exceeds $25,000 (NA to certain foreign organizations) |
| Dissemination of False or Deliberately Misleading Scientific Information (Appropriation Mandate) 4.2.3 | Y | Y | Y |
| Drug-Free Workplace 4.1.7 | Y | NA | NA |

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| Requirement, Objective, or Appropriation Mandate | Grantee | Subaward/ Consortium Participant | Contractor under Grant (routine goods/services) |
|---|---|---|---|
| Earthquake Hazards Reduction Act of 1977 and Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (EO 12699) 10.10 | Y (Construction grants only) | Y | NA |
| Education Amendments of 1972 (Title IX) 4.1.2.2 | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) |
| Endangered Species Act of 1973 10.10 | Y (Construction grants only) | Y | Y |
| Equal Employment Opportunity 10.5 | Y (Construction grants and any grant involving major A&R) | Y | NA If under $10,000 |
| Federal Funding Accountability and Transparency Act (FFATA) 4.1.8 and 8.4.1.4.4 | Y | NA If under $25,000 | NA If under $15,000 |
| Federal Information System Security Management Act 4.1.9 | Y | Y | Y |
| Financial Conflict of Interest 4.1.10 | Y (NA to Phase I of the SBIR/STTR programs and to Federal institutions) | Y | NA |
| Flood Disaster Protection Act of 1973 – Flood Insurance 10.10 | Y (Construction grants only) | NA | NA |
| Fly America Act 4.1.11 | Y | Y | Y |
| Health and Safety Regulations and Guidelines 4.1.12 | Y | Y | Y |
| Health Insurance Portability and Accountability Act (HIPAA) 4.1.4.3 | Y (if a covered entity) | Y (if a covered entity) | Y (if a covered entity) |
| Hotel and Motel Fire Safety Act of 1990 14.6.1 | Y (Conference Grants Only) | Y | Y |

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| Requirement, Objective, or Appropriation Mandate | Grantee | Subaward/ Consortium Participant | Contractor under Grant (routine goods/services) |
|---|---|---|---|
| Human Embryo Research and Cloning Ban (Appropriation Mandate) 4.2.4 | Y | Y | Y |
| Human Stem Cell Research 4.1.13 | Y | Y | Y |
| Human Fetal Tissue Research (Including Transplantation Research) 4.1.14 | Y | Y | Y |
| Human Subjects Protections 4.1.15 | Y | Y | Y |
| Inclusion of Children as Subjects in Clinical Research 4.1.15.7 | Y | Y | NA |
| Inclusion of Women/Minorities as Subjects in Clinical Research 4.1.15.8 | Y | Y | NA |
| Intergovernmental Review of Federal Programs under EO 12372 10.10 | Y (Construction Grants Only) | NA | NA |
| Investigational New Drug Applications/Investigational Device Exceptions 4.1.16 | Y | Y | Y |
| Labor Standards under Federally Assisted Construction 10.5.3 | Y (Construction Grants and major A&R Contracts Exceeding $100,000) | NA | Y |
| Lead-Based Paint Poisoning Prevention Act 10.10 | Y (Construction Grants Only) | Y | Y |
| Limited English Proficiency 4.1.2.5 | Y | Y | NA |
| Lobbying (Federalwide Certification) 4.1.17 | Y Certification required if total costs expected to exceed $100,000 | Y Certification required if greater than $100,000 only | Y Certification required on contracts greater than $100,000 only |
| Lobbying (Appropriation Mandate) 4.2.5 | Y | Y | Y |

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| Requirement, Objective, or Appropriation Mandate | Grantee | Subaward/ Consortium Participant | Contractor under Grant (routine goods/services) |
|---|---|---|---|
| Metric System 4.1.18 and 10.10 | Y | Y | Y |
| Military Recruiting and ROTC Program Access to Institutions of Higher Education 4.1.19 | Y | N | N |
| National Environmental Policy Act of 1969 (including Public Disclosure) 4.1.20 and 10.10 | Y | NA | NA |
| National Historic Preservation Act of 1966 – Archaeological and Historic Preservation Act of 1974 10.10 | Y (Construction Grants; any award involving major or minor A&R, or any work resulting in physical changes to real property) | Y | Y |
| Nondelinquency on Federal Debt 4.1.21 | Y | Y | NA |
| Pro-Children Act of 1994 4.1.22 | Y | Y | Y |
| Promotion or Legalization of Controlled Substances (Appropriation Mandate) 4.2.6 | Y | Y | Y |
| Protection of Wetlands (EO 11990) 10.10 | Y (Construction Grants Only) | Y | Y |
| Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents) 4.1.23 | Y | Y | Y |
| Recombinant DNA Molecules and Human Gene Transfer Research 4.1.24 | Y | Y | Y |
| Rehabilitation Act of 1973 (section 504) 4.1.2.3 and 10.10 | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) | Y (NA to foreign and international organizations) |
| Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees 4.1.25 | Y | Y | NA |

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| Requirement, Objective, or Appropriation Mandate | Grantee | Subaward/ Consortium Participant | Contractor under Grant (routine goods/services) |
|---|---|---|---|
| Research Misconduct 4.1.26 | Y | Y | NA |
| Restriction on Abortions & Exceptions (Appropriation Mandates) 4.2.7 & 4.2.7.1 | Y | Y | Y |
| Restriction on Distribution of Sterile Needles (Appropriation Mandate) 4.2.8 | Y | Y | Y |
| Salary Limitation/Cap (Appropriation Mandate) 4.2.9 | Y | Y | NA |
| Safe Drinking Water Act 10.10 | Y (Construction Grants Only) | Y | Y |
| Seat Belt Use 4.1.27 | Y | NA | NA |
| Select Agents (see Public Health Security & Bioterrorism Preparedness and Response Act) 4.1.23.1 | Y | Y | Y |
| Smoke-Free Workplace 4.1.28 | Y | NA | NA |
| Standards of Conduct 4.1.29 | Y | NA | NA |
| Text Messaging While Driving 4.1.30 | Y | Y | Y |
| Trafficking in Persons 4.1.31 | Y Private entities | Y Private entities | NA |
| Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 10.10 | Y | NA | NA |
| U.S. Flag Air Carriers 7.9.1 | Y | Y | Y |
| USA Patriot Act 4.1.32 | Y | Y | Y |
| Wild and Scenic Rivers Act of 1968 10.10 | Y (Construction Grants Only) | Y | Y |

* NA: A designation of NA in this table indicates that a particular requirement does not apply to an otherwise eligible grantee, consortium participant, or contractor or may not apply because the type of activity covered is one not normally performed by such an entity.

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## 4.1.1 Animal Welfare Requirements

The *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time

of award for all grantee organizations receiving PHS support for research or related activities using live vertebrate animals. Grantee organizations must establish appropriate policies and procedures to ensure the humane care and use of animals, and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

The PHS Policy incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the grantee to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495).

The PHS Policy defines "animal" as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing, or related purposes.

Applications from organizations proposing the use of animals are incomplete if they do not thoroughly address the use of vertebrate animals required in the Research Plan of the application. If the involvement of animals is indefinite at the time of application, the applicant should provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to conducting any animal activities the grantee must submit to the NIH awarding IC for prior approval the detailed information about the use of animals as required in the Research Plan of the application, and meet the Assurance and IACUC approval requirements of the PHS Policy.

No costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and IACUC approval of the activity.

The PHS Policy does not supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research. All grantee organizations are required to comply, as applicable, with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture under the Animal Welfare Act, as amended, 7 U.S.C. 2131 et seq., and other Federal statutes and regulations relating to animals.

#### 4.1.1.1 Animal Welfare Assurance Requirements

An Animal Welfare Assurance is the document submitted by an institution assuring institutional compliance with the PHS Policy. OLAW is responsible for requesting, negotiating, approving or disapproving, and, as necessary, restricting or withdrawing approval of Assurances.

When an applicant institution does not have an Animal Welfare Assurance, the authorized organization representative's signature on the application constitutes declaration that the institution will submit an Assurance when requested by OLAW. Upon such request, the institution shall prepare the Assurance as instructed by OLAW and in accordance with the PHS Policy, and the authorized IACUC shall review those components of the application related to the care and use of animals. Except in certain circumstances, the Assurance must be submitted to and approved by OLAW in order for the IC to award the grant. No costs for activities with live vertebrate animals may be charged to NIH grants in the absence of a valid Assurance on file with OLAW.

If the prime grantee does not have an Assurance and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an Inter-institutional Assurance from OLAW. Under the Inter-institutional Assurance, the grantee and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance.

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#### 4.1.1.2 Verification of IACUC Approval

NIH will delay an award for research involving live vertebrate animals until the grantee organization and all performance sites are operating in accordance with approved Animal Welfare Assurances and the grantee has provided verification of IACUC approval of those sections of the application that involve use of vertebrate animals. IACUC approval must have been granted within three years of the budget period start date to be valid; however, IACUCs may determine that continuing review on a more frequent basis is appropriate.

Verification of IACUC approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of priority score/percentile, applicant organizations with approved Assurances may wish to proceed with IACUC review for those applications that have not yet received IACUC approval and that appear to be in a fundable range.

It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.

No costs for activities with live vertebrate animals may be charged to NIH grants if there is not a valid IACUC approval.

#### 4.1.1.3 Consortiums

Under consortium (subaward) agreements in which the grantee collaborates with one or more other organizations, the grantee, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the grantee as specified in the NIHGPS (see Consortium Agreements chapter in IIB). The animal welfare requirements that apply to grantees also apply to consortium participants and subprojects.

The primary grantee is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. The approval of more than one IACUC is not required if the grantee and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted.

The grantee is further responsible for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).

The list of organizations with approved assurances is available at the OLAW Web site (domestic institutions: http://grants.nih.gov/grants/olaw/assurance/300index.htm, and foreign institutions: http://grants.nih.gov/grants/olaw/assurance/500index.htm).

#### 4.1.1.4 Foreign Grantees and Foreign Performance Sites

Foreign grantees must provide OLAW with an Animal Welfare Assurance for Foreign Institutions. This constitutes institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the *International Guiding Principles for Biomedical Research Involving Animals*. IACUC approval is not required of foreign grantees; however, OLAW encourages foreign grantees to use the standards in the *Guide for the Care and Use of Laboratory Animals*.

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When the grantee is a domestic institution and performance sites are foreign (i.e., domestic grant with a foreign component), PHS Policy requirements are applicable. Accordingly, the grantee remains responsible for animal activity conducted at the foreign site and must provide verification of IACUC approval (i.e., certification that the activity as conducted at the foreign performance site is acceptable to the grantee). The grantee IACUC may accept, as its own, the approval of a foreign organization's IACUC; however, the grantee IACUC remains responsible for the review. Additionally, the foreign site must obtain an Animal Welfare Assurance for Foreign Institutions as described in the preceding paragraph.

#### 4.1.1.5 Reporting to OLAW

Reporting requirements under the PHS Policy include an annual report to OLAW describing any change in the institution's program for animal care and use as described in the Assurance, changes in IACUC membership, and the dates the IACUC conducted its semiannual evaluations of the institution's program and facilities. The IACUC, through the institutional official signing the Assurance, must promptly report any serious or continuing noncompliance with the PHS Policy, serious deviations from the *Guide for the Care and Use of Laboratory Animals*, and any IACUC suspensions.

Charges to NIH grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the grant award are not upheld are not allowable. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.
2. The conduct of animal activities in the absence of a valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

Instances of serious noncompliance with section IV.F.3. of the PHS Policy, such as those mentioned above, are to be reported to OLAW and the IC supporting the grant award. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. NIH requires that reports contain a certification that no unallowable costs were charged to NIH grant funds during a period of noncompliance. If such a certification cannot be made, a detailed accounting of unallowable charges made to each affected grant should be included with the report. If a detailed accounting has not been completed at the time of reporting, a date when it will be provided should be included.

NIH expects grantees to continue to maintain and care for animals during periods when animal activities are conducted in the absence of a valid Animal Welfare Assurance and/or IACUC approval. ICs may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis. Consultation with the IC is encouraged regarding questions concerning allowable costs.

Information about the PHS Policy, Animal Welfare Assurances, and other relevant topics is available from OLAW (see http://grants.nih.gov/grants/olaw/olaw.htm).

### 4.1.2 Civil Rights Protections

Before NIH may make an award to a domestic organization, the AOR must certify, by means of the signature on the application, that the organization has on file with the HHS OCR a one-time Assurance of Compliance with the statutes described in this subsection. The Assurance, Form HHS 690, is filed for the organization and is not required for each application. If the application has been recommended for funding and the applicant organization does not have an Assurance of Compliance on file, it will receive

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the required form and instructions for completion and submission from the awarding IC. The HHS 690 also is available from GrantsInfo@nih.gov or by telephone at 301-435-0714.

Domestic organizations that receive funding from grantees (including consortium participants and contractors under grants) rather than directly from NIH, also are required to file an HHS 690. The applicant/grantee is responsible for determining whether those organizations have the required Assurance on file and, if not, ensuring that it is filed with OCR.

#### 4.1.2.1 Civil Rights Act of 1964

Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR part 80.

#### 4.1.2.2 Education Amendments of 1972

Title IX of the Education Amendments of 1972 provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any educational program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR part 86.

#### 4.1.2.3 Rehabilitation Act of 1973

Section 504 of the Rehabilitation Act of 1973, as amended, provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the physical or mental impairment, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. These requirements pertain to the provision of benefits or services as well as to employment. The HHS implementing regulations are codified at 45 CFR parts 84 and 85.

#### 4.1.2.4 Age Discrimination Act of 1975

The Age Discrimination Act of 1975 prohibits discrimination on the basis of age in any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR part 91.

#### 4.1.2.5 Limited English Proficiency

EO 13166, August 11, 2000, requires grantees receiving Federal financial assistance to take steps to ensure that people with limited English proficiency can meaningfully access health and social services. A program of language assistance should provide for effective communication between the service provider and the person with limited English proficiency to facilitate participation in, and meaningful access to, services. The obligations of grantees are explained on the OCR Web site at http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/.

### 4.1.3 ClinicalTrials.gov Requirement

Under Title VIII, Sec. 801 of Public Law 110-85 (also known as the FDA Amendments Act or FDAAA), section 402(i) of the Public Health Service Act mandates registration and results reporting of certain applicable clinical trials, as defined by law, in the ClinicalTrials.gov registry. This legislation includes a requirement that if an Applicable Clinical Trial is funded in whole or in part by a grant from any agency of the DHHS (including NIH), any grant or progress report shall include a certification that the

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responsible party, as defined by law, has made all required submissions for the Applicable Clinical Trial to ClinicalTrials.gov. Public Law 110-85 also includes registration data elements that must be submitted initially, requires that certain Applicable Clinical Trials also report certain basic results (including adverse event information), and establishes penalties for noncompliance with the law. The signature of the AOR on the application assures compliance with Public Law 110-85, as applicable.

Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Web site (http://prsinfo.clinicaltrials.gov/). A unique identifier called an NCT number will be generated during the registration process.

In summary, FDAAA requires:

- the registration of applicable clinical trials in ClinicalTrials.gov no later than 21 days after the first subject is enrolled,
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA, and
- if an applicable clinical trial is funded in whole or in part by an NIH grant or cooperative agreement, grant and progress report forms shall include a certification that the Responsible Party has made all required submissions to ClinicalTrials.gov.

Applicants and grantees should carefully read instructions in the application guides to determine applicable requirements under FDAAA. While FDAAA only requires registration and results reporting for certain trials, the NIH strongly encourages registration of all clinical trials whether required by law or not.

For additional information, see http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm.

## 4.1.4 Confidentiality

### 4.1.4.1 Certificates of Confidentiality

Section 301(d) of the PHS Act provides that the Secretary may authorize people engaged in biomedical, behavioral, clinical, or other research activities to protect the privacy of research subjects by withholding the names and other identifying characteristics of those subjects from individuals not engaged in the research. Individuals that have such authorization may not be compelled to disclose subjects' names or other identifying characteristics in any Federal, State, or local civil, criminal, administrative, legislative or other proceeding. CoCs may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers from being compelled to disclose information that would identify research subjects, CoCs contribute to achieving research objectives and promote participation in studies by helping to ensure confidentiality and privacy to participants. Information on CoCs is available on the NIH Web site at the CoC Kiosk at http://grants.nih.gov/grants/policy/coc/index.htm. Requests for CoCs should be submitted to the GMO, and, subject to awarding IC review and approval, a certificate may be issued pursuant to section 301(d).

Research subject protections under CoCs differ from those provided under the HIPAA Privacy Rule 42 CFR parts 160 and 164 (HIPAA) and under Section 543 of the PHS Act (see Confidentiality of Alcohol

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and Drug Abuse Patient Records below) by protecting identifiable health information from forced disclosure (e.g., by court order). Therefore, researchers may obtain CoCs to withhold (protect) information that otherwise may be subject to the Privacy Rule or Section 543 of the PHS Act.

#### 4.1.4.2 Confidentiality of Alcohol and Drug Abuse Patient Records

Section 543 of the PHS Act, as implemented in 42 CFR part 2, requires that records of substance abuse patients be kept confidential except under specific circumstances and purposes. These protections differ from those available to patients under HIPAA and are intended to ensure that a patient in a drug or alcohol abuse program is not made more vulnerable than a similar patient who does not seek treatment. The covered records are any information, written or not, of a patient who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program. This includes records of the identity, diagnosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, training, treatment, rehabilitation, or research, which is conducted under an NIH grant. Except as authorized under a court order, no patient record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient. The regulations also describe procedures to allow for nonvoluntary disclosure of certain information by persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs.

#### 4.1.4.3 Confidentiality of Patient Records: Health Insurance Portability and Accountability Act

HHS issued the final version of the "Standards for Privacy of Individually Identifiable Health Information"—the Privacy Rule—on August 14, 2002. The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information. It is administered and enforced by OCR, HHS. Those entities required to comply with the Privacy Rule (classified under the rule as "covered entities") had until April 14, 2003 to do so (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and the grantee organization. The OCR Web site (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including the complete text of the regulation and a set of decision tools for determining whether a particular entity is subject to the rule. An educational booklet, Protecting Heath Information in Research: Understanding the HIPAA Privacy Rule, is available through OCR's Web site and also at http://privacyruleandresearch.nih.gov/. That Web site also includes other educational materials including information specific to grants.

### 4.1.5 Controlled Substances

If controlled substances are proposed to be administered as part of a research protocol or if research is to be conducted on the drugs themselves, applicants/grantees must ensure that the DEA requirements, including registration, inspection, and certification, as applicable, are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC may be reached at 800-882-9539. Information also is available from the National Institute on Drug Abuse at 301-443-6300.

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## 4.1.6 Debarment and Suspension

HHS regulations published in 2 CFR part 376 implement the government-wide debarment and suspension system guidance (2 CFR part 180) for HHS' non-procurement programs and activities. "Non-procurement transactions" include, among other things, grants, cooperative agreements, scholarships, fellowships, and loans. NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, recipients of NIH grants ("primary covered transactions"), including sponsoring institutions for Kirschstein-NRSA individual fellowships, are required to determine whether it or any of its principals (as defined in 2 CFR part 180.995 and 2 CFR part 376.995) is excluded or disqualified from participating in a covered transaction (i.e., grant or cooperative agreement) prior to entering into the covered transaction, i.e., prior to the drawdown of funds which signals acceptance of the grant award. Grantees may decide the method and frequency by which this determination is made and may check the Excluded Parties List System (EPLS) located at https://www.epls.gov/, although checking the EPLS is not required.

Prior to the drawdown of funds for each grant award, grantees must report to the funding IC if the grantee or any of its principals:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 CFR part 180.800(a) or had a civil judgment for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses listed in 2 CFR part 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

Disclosure of unfavorable information by grantees under this requirement will not necessarily cause NIH to deny participation in the grant. NIH will consider the information when determining whether to enter into the covered transaction. NIH will also consider any additional information or explanation that grantees elect to submit with the disclosed information. However, if it is later determined that a grantee failed to disclose information that it knew at the time it accepted the NIH grant award, NIH may (a) terminate the transaction for material failure to comply with the terms and conditions of the award or (b) pursue any other available remedies, including suspension and debarment.

Grantees must immediately report to the NIH funding IC if at any time during the project period, including periods of no-cost extension, they discover that they (a) failed to disclose information prior to the drawdown of funds or (b) due to changed circumstances the grantee or any of its principals for the grant now meet the reporting criteria.

"Lower tier" transactions (e.g., consortiums, subcontracts, consultants, collaborators, and contractors that require the provision of goods or services that will equal or exceed $25,000) also are subject to the HHS regulations. Prior to entering into a lower tier covered transaction with a participant (as defined in 2 CFR part 180.980), grantees must verify that the person (as defined in 2 CFR part 180.985) is not excluded or disqualified. Grantees may not enter into any transaction with a person who is disqualified from that transaction unless an exception under the disqualifying statue, Executive order, or regulation has been obtained from DHHS.

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Grantees must require participants at the next lower tier to (a) comply with the HHS Debarment and Suspension regulations as a condition of participation in the transaction and (b) pass the requirement to comply with the HHS Debarment and Suspension regulations to each person involved in the covered transaction at the next lower tier. Likewise, before entering into such a transaction lower tier participants and contractors under grants (where the contract requires the provision of goods or services that will equal or exceed $25,000) must report to the grantee if it or any participants are presently excluded or disqualified.

Grantees also are required to assure compliance for each trainee under a Kirschstein-NRSA institutional research training grant, or other similar NIH-supported institutional training grant, before their appointment.

Organizations or individuals that are suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants, be paid from NIH grant funds, whether under a primary or lower-tier transaction (including trainees on NIH-supported training grants), or otherwise participate during the period of suspension, debarment, or exclusion. Because individuals who have been debarred, suspended, declared ineligible, or voluntarily excluded from covered transactions may not receive Federal funds for a specified period of time, charges made to the NIH grants for such individuals (e.g., salary) are unallowable.

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## 4.1.7 Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (41 U.S.C. § 701 et seq.) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the AOR agrees that the grantee will provide a drug-free workplace and will comply with the requirement to notify NIH if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. Government wide requirements for Drug-Free Workplace for Financial Assistance are found in 2 CFR part 182; HHS implementing regulations are set forth in 2 CFR part 382.400. All recipients of NIH grant funds must comply with the requirements in Subpart B (or Subpart C if the recipient is an individual) of part 382.

## 4.1.8 Federal Funding Accountability and Transparency Act (FFATA)

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, USASpending.gov. The Web site includes information on each Federal financial assistance award and contract over $25,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and
6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: 1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar

information on all subawards/subcontracts/consortiums over $25,000. Information on the recipient reporting requirement for this law can be found in Monitoring—Reporting—Financial Reports—Recipient Reporting of Subrecipient Data for FFATA.

This requirement is being implemented in accordance with OMB Interim Final Guidance, Federal Register Volume 75, Number 177, September 14, 2010. Full text of the award term is available at 2 CFR part 170.

### 4.1.9 Federal Information Security Management Act

All information systems, electronic or hard copy which contain federal data need to be protected from unauthorized access. This also applies to information associated with NIH grants and contracts. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), Title III of the E-Government Act of 2002 Pub. L. No. 107-347 (beginning on page 48). The applicability of FISMA to NIH grantees applies only when grantees collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. The grantee retains the original data and intellectual property, and is responsible for the security of this data, subject to all applicable laws protecting security, privacy, and research. If and when information collected by a grantee is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information and any derivative copies as required by FISMA.

### 4.1.10 Financial Conflict of Interest

NIH requires grantees and investigators (except Phase I SBIR/STTR applicants and grantees) to comply with the requirements of 42 CFR part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." These requirements promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator, defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS or proposed for such funding. These requirements do not apply to Federal employees and/or Federal agencies. Federal agencies have their own set of rules governing financial conflicts of interest for employees.

The signature of the AOR on the Face Page of the application serves as certification of compliance with the requirements of 42 CFR part 50, Subpart F, including that:

1. There is in effect at the organization a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
2. Prior to the expenditure of any NIH funds under a new award, the organization will report to NIH the existence of any conflicting financial interests of the type covered by 42 CFR part 50.605 and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations;
3. The Institution will continue to make similar reports on subsequently identified conflicts within 60 days of identification;
4. When the institution determines that a financial conflict of interest exists (see #2 and #3 above), the institution must report to the NIH awarding IC through the submission of an FCOI report

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using the eRA Commons FCOI Module. The FCOI report will include the following information:

- Grant number and PD/PI or contact PD/PI if the grant is awarded under the multiple PI model;
- Name of Investigator (if different from the PD/PI) with the FCOI; and
- Method used to protect the involved NIH funded research from bias (i.e., managed, reduced, or eliminated).

5. When requested, the institution will make information available to the NIH regarding all identified conflicting interests and how those interests have been managed, reduced, or eliminated to protect the research from bias.

As described in the regulations, examples of how financial conflicts of interest might be addressed include but are not limited to, the following:

- Public disclosure of significant financial interests
- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification from participation in all or a portion of the research funded by PHS
- Divestiture of significant financial interests
- Severance of relationships that create actual or potential conflicts.

Grantees also must ensure that consortium agreements address whether investigators are subject to the financial conflict of interest requirements of the consortium participant or to those of the grantee (see Consortium Agreements chapter in IIB).

Some IRBs also consider investigator financial conflict of interest in their deliberations, although they are not required to do so (see Public Policy Requirements and Objectives—Human Subjects Protections). These considerations do not replace the Institutional responsibilities as required under the regulation.

Following are some strategies used by IRBs:

- Make IRB members aware of the organization's conflict of interest policies and procedures.
- Include a statement in the informed consent form that all clinical investigators comply with the organizational guidelines.
- Ask investigators to complete a short questionnaire about whether they—or any person responsible for the design, conduct, or reporting of research—have an economic interest in or act as an officer or a director of any outside entity whose financial interest could reasonably appear to be affected by the research.
- Instruct IRB members during their orientation on how to identify and respond to a perceived financial, academic, or other conflict of interest.

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Suggestions for grantees to consider when implementing the requirements of this regulation are available in the NIH publication, Financial Conflict of Interest–Objectivity in Research: Institutional Policy Review, available on the NIH Web site at http://grants.nih.gov/grants/policy/coi/nih_review.htm. Additional information on FCOI including an on-line tutorial and Frequently Asked Questions can be found on OER's Conflict of Interest Web site at http://grants.nih.gov/grants/policy/coi/index.htm.

### 4.1.11 Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible. These circumstances are outlined below:

1. ***Airline "Open Skies" Agreement.*** A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union. This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States. In accordance with the Agreement, however, a U.S.-flag air carrier must be used if: (a) transportation is between points for which there is a city-pair contract fare in effect for air passenger transportation services; or (b) transportation is obtained or funded by the Secretary of Defense or the Secretary of a Military Department. The conditions for use of a Member State airline apply to non-Federal employees as well (e.g., grantees). So, even though grantees are ineligible for city-pair contract fares, they must still use a U.S.-flag air carrier if a city-pair contract fare exists. For information on other "open skies" agreements in which the United States has entered, refer to GSA's Web site: http://www.gsa.gov/portal/content/103191.
2. ***Involuntary Rerouting.*** Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service.
3. ***Travel To and From the U.S.*** Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
4. ***Travel Between Points Outside the U.S.*** Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
5. ***Short Distance Travel.*** For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

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### 4.1.12 Health and Safety Regulations and Guidelines

Grantees are responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR part 1910.1030, Blood borne pathogens; 29 CFR part 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR part 1910. These regulations are available at http://www.osha.gov/comp-links.html.

- Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available at http://www.cdc.gov/OD/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf.

- Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW, Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication can be obtained by telephoning 800-624-8373. It also is available at http://www.nap.edu/catalog/4911.html.

Grantee organizations are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines. However, if requested by the awarding IC, grantees should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.

### 4.1.13 Human Stem Cell Research

Under Executive Order 13505 NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. NIH Guidelines on Human Stem Cell Research, effective July 7, 2009, implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells.

For the purpose of the NIH Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. Induced pluripotent stem cells are human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.

NIH grantees may use hESCs that have been approved by NIH in accord with the NIH Guidelines and are posted on the NIH Human Embryonic Stem Cell Registry, or may establish eligibility of specific cell

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lines for NIH funding by submitting a Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890). Prior to the use of NIH funds, applicants and grantees must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/grantee must provide assurance that one from the NIH Registry will be used.

DHHS regulations for Protection of Human Subjects, 45 CFR part 46, Subpart A, establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. When research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 CFR part 46, Subpart A.

In addition, 45 CFR part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 CFR part 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidance at http://www.hhs.gov/ohrp/policy/index.html#topics.

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#### 4.1.13.1 hESC Research Prohibited with NIH Funding

The following uses of hESCs, even if derived from embryos donated in accordance with the NIH Guidelines and listed on the NIH Registry or human induced pluripotent stem cells, are prohibited:

- Research in which hESCs or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
- Research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line.

In addition, the derivation of stem cells from human embryos is prohibited in NIH funded research by the annual appropriations ban on funding of human embryo research known as the Dickey Wicker Amendment. NIH funding for research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is also prohibited in NIH funded research.

### 4.1.14 Human Fetal Tissue Research

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

NIH guidance for grantees conducting research on human fetal tissue and other information on the governing Federal statute is found in sections 498A and 498B of the PHS Act, 42 U.S.C. 289g-1 and 298g-2.

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements, particularly section 498B. When an application involving human fetal tissue research is submitted to NIH, the AOR's signature certifies that researchers using these tissues are in compliance with section 498B of the PHS Act. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term "valuable consideration" is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

### 4.1.14.1 Research on Transplantation of Human Fetal Tissue

Sections 498A and 498B contain additional legal requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:
    - for therapeutic transplantation research,
    - without any restriction regarding the identity of individuals who may receive the transplantation, and
    - without the donor knowing the identity of the recipient.
- The attending physician must sign a statement that he/she has:
    - obtained the tissue in accordance with the donor's signed statement and
    - fully disclosed to the donor his or her intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.
- In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that he/she:
    - obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
    - did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
    - performed the abortion in accordance with applicable State and local laws.
- The PD/PI must sign a statement certifying that he/she is aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.

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- The PD/PI must certify in writing that he/she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the AOR that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the grantee. This requirement is in addition to the requirements concerning human subjects in research.

In addition, FDA has jurisdiction over fetal cells and tissues intended for use in humans and requests that investigators contact them to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm105857.htm.

### 4.1.15 Human Subjects Protections

The HHS regulations for the protection of human subjects, in 45 CFR part 46, implement Section 491(a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the NIH or other HHS components.

The HHS regulations stipulate that the grantee organization(s), whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in HHS-supported activities (46.101(a) and 46.103(a)). Grantee institutions "engaged" in human subjects research must obtain a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects. An institution is engaged in human subjects research if:

(a) the institution's employees or agents intervene or interact with human subjects for research purposes;

(b) the institution's employees or agents obtain individually identifiable private information about human subjects for research purposes; or

(c) the institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

The OHRP's document entitled Guidance on Engagement of Institutions in Human Subjects Research provides additional guidance on "engagement".

The HHS regulations at Subparts B, C, and D include additional protections for specific populations as follows:

- human fetuses, pregnant women, and neonates (45 CFR part 46, Subpart B);
- prisoners (45 CFR part 46, Subpart C); and
- children (45 CFR part 46, Subpart D).

Certain research activities are exempt from regulatory requirements for an FWA and IRB oversight (45 CFR part 46.101(b)). OHRP guidance states that institutions must adopt clear procedures under which the

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IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations. NIH will make a final determination as to whether proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan.

Unless all research activities meet the criteria for one or more exemptions from 45 CFR part 46, research involving human subjects may only be conducted under an HHS award if the organization has a current OHRP approved FWA and provides certification that an Institutional Review Board (IRB) registered under the specific Assurance has reviewed and approved the proposed activity in accordance with the HHS regulations.

In accepting an award that supports human subjects research, the grantee institution assumes responsibility for all research conducted under the award, including protection of human subjects at all participating and consortium sites, and for ensuring that an FWA and certification of IRB review and approval exists for each site before human subjects research may begin. When consultants are performing research involving human subjects on NIH-funded projects, the consultant's institution must establish an approved FWA.

The NIH Office of Extramural Research Human Subjects Web site contains additional information and Frequently Asked Questions that are available to help investigators understand how these Federal requirements apply to their research. See http://grants.nih.gov/grants/policy/hs/index.htm.

Applications will be considered incomplete if they do not address the involvement of human subjects in the Research Plan of the application. If human subjects research is anticipated within the period of the award but plans for involvement of human subjects cannot be described in the application, applicants must provide a detailed explanation why it is not possible to develop definite plans. Prior to the involvement of human subjects the grantee must submit to the NIH awarding IC for prior approval either (1) detailed information as required in the Research Plan of the application, and meet the FWA and IRB certification requirements, or (2) if all of the research meets the criteria for one or more exemptions, identification of which exemptions(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate.

Grantees may not draw funds from the payment system, request funds from the paying office, or make obligations against Federal funds for research involving human subjects at any site engaged in nonexempt research for any period not covered by both an FWA and IRB approval consistent with 45 CFR part 46. Costs associated with IRB review of human research protocols are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.

The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR part 46.

### 4.1.15.1 Federalwide Assurance Requirements

The Federalwide Assurance (FWA) commits the institution to compliance with the requirements set forth in 45 CFR part 46, and the Terms of Assurance. Each institution that is "engaged" in HHS supported human subjects research must obtain an FWA from OHRP. (See http://www.hhs.gov/ohrp/humansubjects/assurance/ifilasuri.htm.)

When an applicant organization proposes non-exempt human subjects research and does not have a FWA, the AOR signature on the application constitutes declaration that the organization will comply with 45

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CFR part 46 and proceed to obtain a FWA. The NIH awarding component will place a restriction in the NoA so that no human subjects research may be conducted under the award until the FWA and certification of IRB review and approval have been obtained and accepted by NIH.

Each legally separate entity must file its own FWA even if the organization does not operate its own IRB and designates another IRB (registered with OHRP and agreeing to the designation) for that purpose. Affiliated organizations or organizations that will serve as additional performance sites for the grant-supported research also must file an FWA. It is the grantee organization's responsibility to ensure that all sites engaged in research involving human subjects have an appropriate FWA and IRB approval consistent with 45 CFR part 46. It also is the grantee's responsibility to comply with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements). A list of organizations with approved assurances is available at the OHRP Web site (http://www.hhs.gov/ohrp).

No individual may receive NIH grant funds for nonexempt research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an FWA or the individual makes other arrangements with OHRP.

Detailed information concerning FWAs, including the OHRP Assurance Training Module, is available on the OHRP Web site (http://www.hhs.gov/ohrp/).

### 4.1.15.2 Certification of IRB Approval

Grantees must provide a certification to NIH that the research application has been approved by an appropriate IRB, consistent with 45 CFR part 46. IRB approval must have been granted within 12 months before the budget period start date to be valid.

Certification of IRB approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of priority score/percentile, applicant organizations with OHRP FWAs may wish to proceed with IRB review for those applications that have not yet received IRB approval and that appear to be in a fundable range.

The HHS regulations require that the IRB review the actual application or proposal for HHS support (45 CFR part 46.203(f)). OHRP's 5/31/2000 memo *IRB Review of Applications for HHS Support* (http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm)recommends that IRBs ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB.

### 4.1.15.3 Reporting to Funding Agency and OHRP

Under the HHS regulations, grantee institutions must have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the NIH any unanticipated problem involving risks to subjects to others (45 CFR part 46.103(b)(5)). Any IRB suspension or termination of approval must include a statement of the reasons for the IRB's action and must be reported promptly to the investigator, appropriate institutional officials, and any supporting department or agency head (45 CFR part 46.113). Grantee institutions must also file incident reports with OHRP of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 45 CFR part 46 or with the requirements or determinations of the IRB, and suspension or termination of IRB approval. See OHRP 5/27/2005 *Guidance on Reporting Incidents to OHRP* (http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html).

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### 4.1.15.4 OHRP Oversight

OHRP has regulatory responsibility for oversight of grantee compliance with the HHS human subjects regulations. In carrying out this responsibility, OHRP evaluates all written allegations or indications of non-compliance with the HHS regulations it receives from any source. All compliance oversight evaluations are predicated on the HHS regulations and the organization's assurance of compliance. Any corrective actions imposed as a result of compliance oversight evaluations are intended to remedy identified non-compliance and prevent reoccurrence. Because each case is different, OHRP tailors corrective actions to foster the best interest of human research subjects and, to the extent possible, of the organization, research community, and HHS. Most compliance oversight evaluations and resultant corrective actions are resolved at the OHRP level. However, OHRP may recommend actions to be taken by other HHS officials.

Information about the FWA submission process and about OHRP activities related to oversight and compliance, as well as copies of the human subjects regulations, may be obtained from OHRP at the address shown in Part III or from its home page at http://www.hhs.gov/ohrp/. OHRP also has produced an IRB Guidebook and instructional videotapes that may be ordered from OHRP's Web site at http://www.hhs.gov/ohrp/irb/irb_guidebook.htm.

### 4.1.15.5 Education in the Protection of Human Research Participants

Before funds are awarded for competing applications involving human subjects, applicants must submit documentation that all senior/key personnel and senior/key contributors involved in human subjects research have received training in the protection of human subjects. Senior/key personnel include all individuals responsible for the design or conduct of the study, including senior/key personnel of consortium participants or alternate performance sites if they are participating in research that involves human subjects. This documentation should be included in the cover letter signed by the AOR that accompanies the description of other support, IRB and IACUC approval, and other information submitted prior to funding in accordance with Just-in-Time procedures. For non-competing continuation awards, the description of education for new senior/key personnel should be part of the progress report submitted as a prerequisite to award. A free, web-based tutorial that presents information about protections for human participants in research, and satisfies the NIH human subjects training requirement, is found at http://phrp.nihtraining.com/. Additional information about this education requirement is available on the NIH Web site at: http://grants.nih.gov/grants/policy/hs_educ_faq.htm.

### 4.1.15.6 Data and Safety Monitoring

The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. The NIH policies on data and safety monitoring specify that the level and frequency of monitoring should be commensurate with the risks, nature, and complexity of the clinical trial, and are in addition to any monitoring requirements imposed by FDA or the *NIH Guidelines for Research Involving Recombinant DNA Molecules*. There are a number of options for monitoring clinical trials including, but not limited to, monitoring by a/an:

- PD/PI (required),
- IRB (required),
- Independent individual/safety officer,
- Designated medical monitor,

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- Internal committee or board with explicit guidelines,
- DSMB (required for multi-site trials).

Applications that include clinical trials must include a general description of the data and safety monitoring plan. The description of the data and safety monitoring plan in competing applications will be reviewed by the SRG. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It must describe the entity that will be responsible for monitoring and how adverse events will be reported to the IRB, the NIH and, when appropriate, follow OBA guidelines, and FDA regulations for INDs and IDEs.

A detailed monitoring plan must be included as part of the research protocol, be submitted to the local IRB, and be reviewed and approved by the NIH awarding IC prior to the accrual of human subjects. The awarding IC may specify the reporting requirements for adverse events, which are in addition to the annual report to the IRB. The clinical trial monitoring function is above and beyond that traditionally provided by IRBs; however, the IRB must be cognizant of the procedures used by clinical trial monitoring entities and the monitor must provide periodic reports to investigators for transmittal to the local IRB.

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

For multi-site Phase I and II trials, investigators should organize a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and the IRBs of participating sites. The frequency of summary reports will depend on the nature of the trial. Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and II clinical trials. However, such plans always should be evaluated for appropriateness for the particular investigation.

All multi-site trials with DSMBs are expected to forward summary reports of adverse events to individual IRBs so they can address reports related to the site for which they have responsibility. Grantees should address questions on this subject to the NIH PO.

Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

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### 4.1.15.7 Inclusion of Children as Subjects in Clinical Research

NIH-conducted or supported clinical research must adhere to the *NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects*. The goal of the Policy is to increase the participation of children in research so that adequate data will be developed to support the cause, treatment and cure of diseases that affect children (http://grants.nih.gov/grants/funding/children/children.htm). NIH supported clinical research must include children in the research design unless there are scientific or ethical reasons not to include them. For the purpose of this policy requirement a child is defined as an individual under the age of 21 years.

The involvement of children in clinical research must be in compliance with all applicable provisions of pertinent Federal laws and regulations, including the HHS human subjects regulations at 45 CFR part 46 Subpart D, which addresses additional protections for children who participate as subjects in research.

Investigative teams are to have expertise in dealing with children of the ages included as subjects, facilities to must be appropriate to accommodate the children, and there must be inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

#### 4.1.15.8 Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender and Racial Ethnic Participation

NIH-conducted and –supported Clinical research must conform to the *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research* (http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm), in accord with section 492B of the PHS Act, added by the NIH Revitalization Act of 1993. The policy requires that women and members of minority groups and their subpopulations be included in NIH-conducted or supported clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the NIH IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification.

Cost is not an acceptable reason for exclusion except when the research would duplicate existing data. Women of childbearing potential should not be routinely excluded from participation in clinical research. The policy applies to research subjects of all ages in NIH-supported clinical research studies (see definition of clinical research). The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. A proposed outreach program for recruiting women and minorities as participants should also be included. When an NIH-defined Phase III clinical trial is proposed, investigators must consider whether clinically important sex/gender and race/ethnicity differences in the intervention effect are to be expected and plan the research accordingly.

Investigators must also collect and annually report information on sex/gender, race, and ethnicity in clinical research studies. The OMB minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant project is described in OMB Directive No. 15. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards include five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for ethnicity: “Hispanic or Latino,” and “Not Hispanic or Latino.”

### 4.1.16 Investigational New Drug Applications/Investigational Device Exceptions

To be eligible for NIH funding, all clinical research involving investigational drugs and devices, or other products regulated by the FDA, must comply with all applicable FDA requirements, including those for INDs, IDEs, and human subject protection. Among other provisions, FDA regulations for human subjects protection are published in 21 CFR parts 50 and 56 with additional standards found in parts 312 and 812.

When applicable, the sponsor of the IND/IDE, whether NIH, a grantee, or a third party, is legally responsible for meeting the FDA requirements for sponsors. If the sponsor is also the PI, then the sponsor will need to satisfy FDA’s requirements for sponsor-investigators. If the IND/IDE sponsor is a third party, such as a pharmaceutical company or research organization under contract to a grantee or to a pharmaceutical company, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the sponsor rather than the grantee. This generally will be the case for larger, multi-site clinical trials. If the grantee is the IND/IDE holder, commonly referred to as an “investigator-initiated IND/IDE,” the grantee or the investigator serves as the sponsor and assumes the legal responsibility. In any case, the

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grantee is ultimately responsible to NIH for ensuring compliance with the applicable requirements for protection of human subjects, including compliance with FDA's requirements.

Following the filing of an IND, FDA has a 30-day period in which to review it. FDA may allow the IND to proceed or may defer approval of the IND until changes it deems acceptable are made. FDA also may order a clinical trial to be suspended or terminated, at any time, based on information it receives about that clinical trial.

When NIH funds any part of a clinical study involving an IND or an IDE, NIH must be knowledgeable about any significant communications with FDA concerning the study. The grantee organization must report certain types of FDA communications to the NIH awarding IC within 72 hours of receiving a copy of or upon being informed of the FDA communication (through the PD/PI or another person acting on behalf of the grantee), whichever occurs first. This notification requirement applies to any of the following communications from FDA with the sponsor of the IND or IDE:

- Warning letters (whether sent to the grantee or to the commercial sponsor)
- Notices of Initiation of Disqualification Proceedings and Opportunity to Explain
- Notice of Opportunity for Hearing
- Notice of Disqualification
- Consent Agreements
- Clinical hold letters that pertain to breaches of good manufacturing practices, good clinical practices, or other major issue requiring significant changes in the protocol.

The notification should be made in writing, but also may be done by telephone if a written notice would delay the notification. It should include a statement of the action taken or contemplated and the assistance needed to resolve the situation. These requirements apply to the grantee even if the grantee or the NIH-funded PD/PI is the sponsor. Failure to comply with this requirement may result in NIH imposing a corrective and/or enforcement action (see Administrative Requirements—Enforcement Actions). FDA communications are considered grant-related records for purposes of retention and access (see Administrative Requirements—Monitoring—Record Retention and Access).

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### 4.1.17 Lobbying Prohibition

Recipients of Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR part 93, which also describes types of activities, such as legislative liaison activities and professional and technical services, which are not subject to this prohibition.

Applicants for NIH awards with total costs expected to exceed $100,000 are required to certify that they

- have not made, and will not make, such a prohibited payment;

- will be responsible for reporting the use of non-appropriated funds for such purposes; and
- will include these requirements in consortium agreements and contracts under grants that will exceed $100,000 and obtain necessary certifications from those consortium participants and contractors.

The signature of the AOR on the application serves as the required certification of compliance for the applicant organization. Disclosure reporting is addressed in Administrative Requirements—Monitoring—Reporting.

See also Legislative Mandates section for an additional restriction concerning Lobbying.

### 4.1.18 Metric System

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, measurement values in applications and grantee-prepared reports, publications, and other grant-related documents should be in metric. See Construction Grants chapter in IIB for requirements for metric usage in construction activities.

### 4.1.19 Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education

Section 588 of the National Defense Authorization Act of 1995, amended (10 U.S.C. §983), precludes NIH grant awards to institutions of higher education that DoD determines have an anti-Reserve Officer Training Corps (ROTC) policy or practice (regardless of when implemented) that either prohibits or, in effect, prevents the Secretary of Defense from gaining entry to campuses or access to students or information for military recruiting. DoD publishes each determination of ineligibility in the *Federal Register* as well as publishing, once every 6 months, a list of all currently ineligible schools. If DoD determines that an institution is ineligible during an ongoing project period, NIH will suspend support of current and future grant awards as provided in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support. Funding eligibility may be restored on the basis of new information provided by DoD.

### 4.1.20 National Environmental Policy Act

All NIH grants, whether or not they include construction or major A&R activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended. This Act requires Federal agencies to consider the reasonably foreseeable environmental consequences of all grant-supported activities. As part of NIH's implementation of this Act, grantees are required to promptly notify NIH of any reasonably foreseeable impacts on the environment from grant-supported activities, or certify that no such impacts will arise upon receipt of a grant award. In addition, NIH has determined that most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.

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4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

This requirement is in addition to other public policy requirements for grants for construction and alteration and renovation activities discussed more fully in the Construction chapter - Construction, Modernization, or Major Alteration and Renovation of Research Facilities—Public Policy Requirements.

## 4.1.21 Nondelinquency on Federal Debt

The Federal Debt Collection Procedures Act of 1990 (Act), 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the AOR of the applicant organization (or individual in the case of a Kirschstein-NRSA individual fellowship) certifies, by means of his/her signature on the application, that the organization (or individual) is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or satisfactory arrangements made, NIH will take that delinquency into account when determining whether the applicant would be a responsible NIH grant recipient.

Anyone who has been judged to be in default on a Federal debt and who has had a judgment lien filed against him or her should not be listed as a participant in an application for an NIH grant until the judgment is paid in full or is otherwise satisfied. No funds may be used for or rebudgeted following an award to pay such an individual. NIH will disallow costs charged to awards that provide funds to individuals in violation of this Act.

These requirements apply to all types of organizations and awards, including foreign grants.

## 4.1.22 Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH grants are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol

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treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH grant should be directed to the GMO.

## 4.1.23 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. 201 note, is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the U.S. homeland or other criminal acts. The Act was implemented, in part, through regulations published by HHS and USDA at 42 CFR part 73, 9 CFR part 121 and 7 CFR part 331 or commonly referred to as "Select Agent Regulations." Copies of these regulations are available at http://www.selectagents.gov/Regulations.html, or can be obtained from CDC, 1600 Clifton Road, MS A-46, Atlanta, GA 30333; telephone: 404-718-2000.

Research involving select agents and recombinant DNA molecules also is subject to the *NIH Guidelines for Research Involving DNA Molecules* (NIH Guidelines) (see Recombinant DNA Molecules, Research Involving (including Human Gene Transfer Research) in this section for applicability of these guidelines). The NIH Guidelines apply to (1) research projects involving recombinant DNA that are conducted at or sponsored by an organization that receives NIH support for recombinant DNA research (for research performed abroad, the NIH Guidelines apply if the research is supported by NIH funds) and (2) research projects involving testing in humans of materials containing recombinant DNA developed with NIH funds, if the organization that developed the materials sponsors or participates in those projects. The NIH Guidelines are available at http://oba.od.nih.gov/oba/index.html.

### 4.1.23.1 Select Agents

#### 4.1.23.1.1 Select Agent Awards to U.S. Institutions

Domestic grantees who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR part 73 and 9 CFR part 121 and Section 3 of 7 CFR part 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

#### 4.1.23.1.2 Select Agent Awards to Foreign Institutions and International Organizations

Foreign Institutions and International Organizations who conduct research involving select agents (see 42 CFR part 73 for the select agent list; and 7 CFR part 331 and 9 CFR part 121 for the relevant animal and plant pathogens) must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR part 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by NIH funds before using these funds for any work directly involving select agents. Grantees must be willing to address the following key elements appropriate for their institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR part 73. If this

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work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to the NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

#### 4.1.23.1.3 Select Agent Awards to U.S. Institutions with Foreign Subcomponents

Grantees who conduct research involving select agents (see 42 CFR part 73 for the select agent list; and 7 CFR part 331 and 9 CFR part 121 for the relevant animal and plant pathogens) must complete registration with CDC (or USDA, depending on the agent) before using NIH funds for any work directly involving the select agent at the U.S. institution. No funds can be used for research involving select agents if the final registration certificate is denied. Before using NIH funds for any work directly involving the select agents at a foreign subrecipient, the U.S. grantee must provide information from the foreign institution satisfactory to the NIH that a process equivalent to that described in 42 CFR part 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by these funds. Grantees must be willing to address the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR part 73. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to the NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

## 4.1.24 Recombinant DNA Molecules, Research Involving (including Human Gene Transfer Research)

### 4.1.24.1 Scope and Applicability

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines) (September 2009 or latest revision) apply to all research projects that involve recombinant DNA and are conducted at or sponsored by an organization that receives NIH support for recombinant DNA research. A copy of the NIH Guidelines is available at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html.

As defined by the NIH Guidelines, recombinant DNA molecules are either (1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or (2) molecules that result from the replication of those described in (1). The NIH Guidelines apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the NIH Guidelines.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant DNA research at the organization, or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization. Two specific requirements of the NIH Guidelines are discussed below, but the grantee should carefully review the NIH Guidelines in their entirety to ensure compliance with all of the requirements for projects involving recombinant DNA techniques.

Recombinant DNA research involving select agents also is subject to pertinent CDC and USDA regulations, 42 CFR part 73, Select Agents and Toxins; and 7 CFR part 331 and 9 CFR part 121, Possession, Use, and Transfer of Biological Agents and Toxins.

### 4.1.24.2 Institutional Biosafety Committee

Each organization that conducts research involving recombinant DNA, including contractors under grants, must have policies and procedures to ensure compliance with the NIH Guidelines and must

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establish a standing IBC. The IBC is required to review each proposed project for recombinant DNA experiments to ensure that the procedures, project, personnel, and facilities are adequate and in compliance with the NIH Guidelines. Section IV of the NIH Guidelines specifies the composition of IBCs. A roster of the IBC members and biosketches for each member must be submitted to the NIH's Office of Biotechnology Activities (OBA). At a minimum, the roster should indicate the name of each IBC member, as well as which IBC members are serving as the chairperson, contact person, and, as applicable, experts in biosafety or plant, animal, or human experimentation. Biosketches should include a description of the occupation and professional qualifications of each member.

#### 4.1.24.3 Investigators and Institutional Staff

Section IV of the NIH Guidelines also specifies the roles and responsibilities of PD/PIs, biological safety officers (BSOs) and grantee institutions with respect to the safe conduct and oversight of recombinant DNA research. Investigators, laboratory staff, BSOs, and institutional officials should read and be aware of their duties and expected biosafety practices, as described by the NIH Guidelines.

#### 4.1.24.4 Safety and Annual Reporting

Appendix M-I-C-4 of the NIH Guidelines requires PD/PIs to report serious adverse events that are unexpected and are possibly associated with human gene transfer intervention to OBA and the IBC within 15 calendar days of investigator notification of the sponsor, or within 7 days if life-threatening or fatal. In addition, annually, investigators must submit to OBA certain information about protocols. Further information about the content of these reports can be found in Appendix M-I-C-3 of the NIH Guidelines. Investigators may use GeMCRIS database (http://www.gemcris.od.nih.gov/) as an electronic tool to report adverse events on human gene transfer trials to NIH OBA.

### 4.1.25 Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees

As required by Section 403C of the Public Health Service Act, each institution receiving an NIH award for the training of graduate students for doctoral degrees must provide information on completion rates and time to degree to all applicants to doctoral programs supported by NIH training awards. Specifically, institutions must provide applicants with the following information for the programs to which they apply:

- The percentage of students admitted for study who successfully attain a doctoral degree, and
- The average time (not including any leaves of absence) between the beginning of graduate study and the receipt of a doctoral degree.

Institutions **affected** by this Assurance and information disclosure requirement are doctoral degree granting institutions that receive any of the following institutional training grant awards or cooperative agreements from the NIH for the doctoral training of graduate students:

D43, TU2, T15, T32, T37, T90, U2R, U90, and U54/TL1

Institutions are **not affected** by this requirement if they:

- Receive only individual NIH fellowship awards.

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- Provide training only to undergraduate or master's level students supported through one of the activity codes listed above.
- Provide only short-term training to doctoral-level health professional students through one of the activity codes listed above.
- Receive an award for one or more of the activity codes for doctoral training of graduate students, but do not confer doctoral degrees themselves (e.g., teaching hospitals).
- Receive an institutional training grant award for doctoral training of graduate students from a Public Health Service Agency other than the NIH.

In complying with this Assurance and information disclosure requirement, institutions may decide how best to present the required information to applicants and may wish to consider consolidating data by department or broad program to which candidates apply, or providing additional information in order to provide context.

Grantees with awards for any of the activity codes listed above are also required to provide corresponding information on trainees supported by each of their awards when submitting a renewal application or non-competing continuation progress report (PHS 2590).

### 4.1.26 Research Misconduct

Title 42 CFR part 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions" specifies grantee responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity, and take all reasonable and practical steps to foster research integrity. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The HHS Office of Research Integrity (ORI) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities (http://www.ori.dhhs.gov).

To be eligible for PHS funding an institution must have an assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of research misconduct in PHS-supported research that complies with 42 CFR part 93. An institution establishes an assurance when an official signs the face-page (SF 424 (R&R) or PHS 398) of the grant application form or when the institution files a separate assurance form. Once established, institutions maintain their assurance by filing the Annual Report on Possible Research Misconduct (between January 1 and March 1 each year), submitting their policy for responding to allegations of research misconduct for review when requested by ORI, revising their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and complying with the PHS regulation.

As stated throughout the NIHGPS, the grantee has primary responsibility for ensuring that it is conducting its NIH-funded project in accordance with the approved application and budget and the terms and conditions of the award. The grantee must carry out its responsibilities with extra care where research misconduct has been found or where a research misconduct investigation has been initiated, as specified in 42 CFR part 93, Subpart C. The grantee must report promptly to ORI any decision to initiate an investigation of research misconduct.

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The regulations specify the timing of an institutional investigation, related reporting to ORI, notice to the respondent, custody of records, documentation, opportunity for respondent to comment on the report, and the components on a final institutional investigative report.

If a misconduct investigation is initiated, the grantee must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and live vertebrate animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to help grantees with investigating and reporting on research misconduct, and IC staff members are available to provide technical assistance and to work with grantees to protect funded projects from the adverse effects of research misconduct.

The grantee is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. When the grantee finds research misconduct by anyone working on an NIH grant-supported project, whether at the grantee organization or at a third-party organization, the grantee must assess the effect of that finding on the ability to continue that project, as originally approved by NIH, and must promptly obtain NIH approval of any intended change of PD/PI or other senior/key personnel. Examples of possible sanctions by NIH are withdrawal of approval of the PD/PI or other senior/key personnel, debarment, disallowance of costs associated with the invalid or unreliable research, withholding of a continuation award, or suspension or termination, in whole or in part, of the current award. These actions are described in Administrative Requirements—Enforcement Actions.

Where research misconduct has affected data validity or reliability, ORI or NIH may require the grantee and its employee/collaborator authors to submit a correction or retraction of the data to a journal, publish the corrected data, or both. If the grantee does not comply with this requirement, NIH may invoke its rights, under 45 CFR part 74 or 92, to access the data (including copyrightable material developed under the award), have the data reviewed, and submit the correction.

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## 4.1.27 Seat Belt Use

Pursuant to EO 13043 (April 16, 1997), Increasing the Use of Seat Belts in the United States, NIH encourages grantees to adopt and enforce on-the-job seat belt policies and programs for their employees when operating vehicles, whether organizationally owned or rented or personally owned.

## 4.1.28 Smoke-Free Workplace

NIH strongly encourages grantees to provide smoke-free workplaces and to promote the nonuse of tobacco products. NIH defines the term “workplace” to mean office space (including private offices and other workspace), conference or meeting rooms, corridors, stairways, lobbies, rest rooms, cafeterias, and other public spaces.

## 4.1.29 Standards of Conduct

NIH requires grantees to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, NIH does not require a grantee to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State and local laws and cover, at a

minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas as political participation and bribery. The standards also must do the following:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper.
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official.
- Include a process for notification and review by the responsible official of potential or actual violations of the standards.
- Specify the nature of penalties that the grantee may impose. These penalties would be in addition to any penalties that NIH or a cognizant Federal agency may impose for infractions that also violate the terms or conditions of award.

The grantee is not required to submit its general standards of conduct to NIH for review or approval. However, a copy must be made available to each of its officers, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, to NIH. The grantee is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the IC CGMO if the infraction is related to an NIH award. (A listing of the NIH GMOs is available at http://grants.nih.gov/grants/stafflist_gmos.htm.) If a suspension or separation action is taken by a grantee against a PD/PI or other senior/key personnel under an NIH grant, the grantee must request prior approval of the proposed replacement as specified in Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements.

The grantee must promptly report issues involving potential criminal violations, such as misappropriation of Federal funds, to the HHS OIG .

## 4.1.30 Text Messaging While Driving

Executive Order 13513 (E.O. 13513) requires each Federal agency to encourage contractors, subcontractors, and grant and cooperative agreement recipients and subrecipients to adopt and enforce policies that ban text messaging while driving company-owned or -rented vehicles or Government Owned Vehicles, or while driving Personally Owned Vehicles when on official Government business or when performing any work for or on behalf of the Government.

To further the requirement of encouraging such policies, the NIH encourages grantees to consider new rules and programs, reevaluate existing programs to prohibit text messaging while driving, and conduct education, awareness, and other outreach for employees about the risks associated with texting while driving. These initiatives should encourage voluntary compliance with the grantee agency's text messaging policy while off duty.

For the purposes of this policy and pursuant to E.O. 13513, the following definitions apply:

(a) ''Texting'' or ''Text Messaging'' means reading from or entering data into any handheld or other electronic device, including for the purpose of SMS texting, e-mailing, instant messaging, obtaining navigational information, or engaging in any other form of electronic data retrieval or electronic data communication.

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(b) ‘‘Driving’’ means operating a motor vehicle on an active roadway with the motor running, including while temporarily stationary because of traffic, a traffic light or stop sign, or otherwise. It does not include operating a motor vehicle with or without the motor running when one has pulled over to the side of, or off, an active roadway and has halted in a location where one can safely remain stationary.

### 4.1.31 Trafficking in Persons

This government-wide award term implements Section 106 (g) of the Trafficking Victims Protection Act (TVPA) of 2000, as amended (22 U.S.C. 7104), located at 2 CFR part 175. This is implemented in accordance with OMB Interim Final Guidance, Federal Register Volume 72, No. 218, November 13, 2007. A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance.

In accordance with the statutory requirement, in each agency award under which funding is provided to a private entity, section 106(g) of the TVPA, as amended, requires the agency to include a condition that authorizes the agency to terminate the award, without penalty, if the recipient or a subrecipient —

(a) Engages in severe forms of trafficking in persons during the period of time that the award is in effect;

(b) Procures a commercial sex act during the period of time that the award is in effect; or

(c) Uses forced labor in the performance of the award or subawards under the award.

Full text of the award term is provided at 2 CFR part 175.15.

### 4.1.32 USA Patriot Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. “Restricted persons,” as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent (see Public Health Security and Bioterrorism Preparedness and Response Act in this section).

## 4.2 APPROPRIATION MANDATES

The following statutory provisions limit the use of funds on NIH grants, cooperative agreements, and contract awards. These are provided separately in this section since they are subject to change annually based on specific appropriation language that restricts the use of grant funds. References to “Act” in these sections refer to the governing HHS annual appropriation Act. A list of Appropriation Mandates applicable to each fiscal year can be found on the OER Web site.

### 4.2.1 Acknowledgment of Federal Funding

All HHS grantees must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Grantees are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

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See also Availability of Research Results—Rights In Data (Publication and Copyrighting) for additional information on acknowledging NIH grant support for each publication that results from NIH grant-supported research.

### 4.2.2 Certification of Filing and Payment of Taxes

None of the funds appropriated or otherwise made available by the governing appropriation Act may be used to enter into a contract in an amount greater than $5,000,000 or to award a grant in excess of such amount unless the prospective contractor or grantee certifies in writing to NIH that, to the best of its knowledge and belief, the contractor or grantee has filed all Federal tax returns required during the 3 years preceding the certification, has not been convicted of a criminal offense under the Internal Revenue Code of 1986, and has not more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding.

### 4.2.3 Dissemination of False or Deliberately Misleading Scientific Information

None of the funds made available in the governing appropriations Act may be used to disseminate scientific information that is deliberately false or misleading

### 4.2.4 Human Embryo Research and Cloning Ban

NIH funds may not be used to support human embryo research. NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR part 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism not protected as a human subject under 45 CFR part 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

In addition to the statutory restrictions on human fetal research under subsection 498((b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

### 4.2.5 Lobbying—Appropriation Prohibition

NIH appropriated funds may not be used, other than for normal and recognized executive-legislative relationships for publicity or propaganda purposes, for the preparation, distortion, or use of an kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself. No part of any governing appropriation Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature. Also see Public Policy Requirements and Objectives—Lobbying Prohibition and Cost Considerations—Allowability of Costs and Activities—Selected Items of Cost.

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## 4.2.6 Promotion or Legalization of Controlled Substances

Grantees are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedule of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the grantee notifies the GMO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage (see also Public Policy Requirements/Controlled Substances).

## 4.2.7 Restriction on Abortion Funding

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion. The term ''health benefits coverage'' means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

### 4.2.7.1 Exceptions to Restrictions on Abortions

(a) The limitations established in the preceding section shall not apply to an abortion— (1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State's or locality's contribution of Medicaid matching funds).

(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).

(d)(1) None of the funds appropriated to NIH may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. (2) In this subsection, the term ''health care entity'' includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

## 4.2.8 Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by the local public health or local law enforcement authorities to be inappropriate for such distribution.

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### 4.2.9 Salary Cap/Salary Limitation

None of the funds appropriated in the governing appropriation Act for the NIH, shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level 1. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of Executive Level 1 per year will be adjusted in accordance with the legislative salary limitation. Current and historical information on the applicable salary cap for each fiscal year is found on the OER Salary Cap Summary webpage.

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# 5 THE NOTICE OF AWARD

The Notice of Award (NoA) is the legal document issued to notify the grantee that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. The NoA reflects any future-year commitments. A revised NoA may be issued during a budget period to effect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. NIH will not issue a revised NoA to reflect a grantee's post-award rebudgeting. Until an IC has issued the NoA for the initial award, any costs incurred by the applicant for the project are incurred at its own risk (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs for NIH policy on the allowability of pre-award costs).

The NoA sets forth pertinent information about the grant, including, but not limited to, the following:

- Application/grant identification number (grant number)
- Name of grantee organization
- Name(s) of the PD/PI(s)
- Name(s) of Senior/key personnel that are subject to NIH prior approval requirements if a significant change in level of effort occurs
- Approved project period and budget period start and end dates
- Amount of funds authorized for obligation by the grantee
- Amount of anticipated future-year commitments (if applicable)
- Names of the cognizant IC PO, GMO, and GMS
- Applicable terms and conditions of award, either by reference or inclusion
- Any restriction on the use of funds

A grantee indicates acceptance of an NIH award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. If the grantee cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the GMO immediately upon receipt of the NoA. If resolution cannot be reached, the GMO will void the grant. NIH's determination of applicable terms and conditions of award or a GMO's denial of a request to change the terms and conditions is discretionary and not subject to appeal (post-award appeal rights are discussed in Administrative Requirements—Grant Appeals Procedures). Once the award is accepted by the grantee, the contents of the NoA are binding on the grantee unless and until modified by a revised NoA signed by the GMO.

## 5.1 NOTICE OF AWARD NOTIFICATION

NIH notifies the grantee organization via e-mail when an award has been issued. In order to allow for the e-mail notification of the NoA, grantee organizations must register a valid e-mail address in the NoA E-

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mail field in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. Organizations are encouraged to use a unique e-mail address that is not specific to an individual in order to avoid communication problems when personnel change. It is the responsibility of the grantee organization to maintain a current and accurate e-mail address for NoAs. NIH will not distribute NoAs other than through this system-generated e-mail notification process. Grantees that do not maintain a current NoA notification e-mail address will be responsible for accessing NoAs via the eRA Common.

When NIH issues the NoA, the document is made available to grantee officials and corresponding PD/PIs in the eRA Commons through the Status module. The eRA Commons is the official repository for the NoA document.

In addition to e-mail notifications, there is a public query *Issued Notice of (Grant) Award* (http://era.nih.gov/commons/quick_queries/NIH_issued-NGAs.cfm) available on the eRA Web site to generate a list of awards issued to an organization over a selected period. The organization's Institution Profile File (IPF) Number is required in order to use the query.

## 5.2 ASSOCIATED APPLICATIONS AND/OR AWARDS

For some special initiatives a project or program may be funded by multiple awards that are associated with the others through special terms and conditions. These terms include any reporting requirements that would need to be coordinated in future years. When multiple awards are issued for a particular project/program at different institutions, the coordination required among the grantee institutions administering the awards will be documented in the special terms and conditions.

## 5.3 FUNDING

For most grants, NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget periods. The length of an initial project period (competitive segment) or of any subsequent competitive segment is determined by the NIH awarding IC on the basis of:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete the project,
- limitation on the length of the project period recommended by the peer reviewers,
- the awarding IC's programmatic determination of the frequency of competitive review desirable for managing the project, and
- NIH funding principles.

The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. NIH policy limits each competitive segment to a maximum of 5 years (exclusive of non-competing extensions). A single award covering the entire period of support generally is used only if the project is solely for construction or A&R of real property, if the total planned period of support will be less than 18 months, or if the project is awarded under a special support mechanism.

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The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for compelling programmatic or administrative reasons. The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award and any allowable cost of living escalation for recurring costs. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Grantees are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Report). A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future-year commitments. NIH may decide to withhold support for one or more of the reasons cited in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support. A grantee may appeal this decision only if the withholding was for the grantee's failure to comply with the terms and conditions of a previous award (see Administrative Requirements—Grant Appeals Procedures).

## 5.4 BUDGET

Each NoA sets forth the amount of funds awarded. The amount may be shown either as a categorical (line item) budget or as an amount for total direct costs (not broken down by category) and an amount for F&A costs, if applicable. Modular awards represent a type of award made without a categorical budget (see Modular Applications and Awards chapter in IIB). The grantee has certain rebudgeting flexibility within the overall amount awarded (see Administrative Requirements—Changes in Project and Budget). The grantee may be required to provide matching funds under construction awards as specified in Construction Grants—Matching in IIB as well as under other NIH programs or awards if specified in the funding opportunity announcement.

## 5.5 ADDITIONAL TERMS AND CONDITIONS

In addition to, or in lieu of, the standard terms and conditions of award specified in the NIHGPS, NIH may use terms and conditions for program-specific or award-specific reasons. For example, if, on the basis of a grantee's application or other available information, the GMO finds—at the time of award or at any time subsequent to award—that the grantee's management systems and practices are not adequate to ensure the appropriate stewardship of NIH funds or to achieve the objectives of the award, the GMO may impose special, more restrictive terms and conditions on the award in accordance with 42 CFR part 52.9 and 45 CFR part 74.14 or 92.12. For example, NIH could require a grantee to obtain prior approval for expenditures that ordinarily do not require such approval or to provide more frequent reports. In addition to closer monitoring, NIH may assist the grantee in taking any necessary corrective action.

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# 6 PAYMENT

The PMS is a centralized grants payment and cash management system, operated by HHS PSC, DPM. HHS grant payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis, as specified in the NoA and as described in this chapter. Payments under NIH grants generally are made as advance payments. Except as indicated in this chapter, NIH grant payments are made by PMS, operated by PSC,DPM, in accordance with Department of the Treasury and OMB requirements, as implemented by 45 CFR parts 74.22 and 92.21. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal government and disbursement by a grantee. Therefore, although the grant may be financed by advance payments, the intent is that grantees draw funds on an as-needed basis—specifically, no more than 3 days before the funds are needed.

All Federal funds deposited by PMS in a grantee's bank account as an unrestricted advance payment should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next workday after receipt of the funds. The potential for excessive Federal cash on hand exists each time a grantee does not disburse Federal funds in this manner. The grantee is responsible for determining when the Federal funds have been deposited into its bank account for each drawdown, ensuring that the funds are fully disbursed by the close of business the next workday after they are received, and immediately returning all undisbursed Federal funds to PMS.

The Treasury and OMB policies also establish accountability for interest earned on advances of grant funds and provide for use of the reimbursement method if cash management requirements are not met. Advances made by grantees to consortium participants and contractors under grants must conform to substantially the same standards of timing and amount that govern advances to the grantee.

Operational guidance for recipients is provided through a training CD from PSC. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds through the Federal Financial Report (SF 425) should be directed to PSC/DPM (see Part III).

OFM makes payments under grants to foreign or international organizations, awards to individuals, and awards to agencies of the Federal government.

## 6.1 SMARTLINK II/ACH

The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to a grantee's bank account and requires grantees to have Internet access to submit a request for funds to PMS. SMARTLINK II/ACH provides funds the day following the request with direct deposit using the Federal Reserve Bank's (Richmond, Virginia) ACH process.

## 6.2 CASH REQUEST

Grantees not eligible for an unrestricted advance of funds by SMARTLINK II/ACH must submit a cash request, usually monthly. The cash request may be on either an advance or reimbursement basis, as specified by the NIH awarding IC. Cash requests are used when a grantee's cash management must be closely monitored (for example, grantees whose financial management systems do not meet the standards specified in 45 CFR part 74.21 or 92.20) or under programs where reimbursement financing is appropriate. A grantee also may be converted from an unrestricted advance payment method to a cash request basis if, during post-award administration, the GMO determines that a grantee is not complying

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with the cash management requirements or other requirements of the award, including the submission of complete and timely reports (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Enforcement Actions—Modification of the Terms of Award).

If the cash request is for an advance payment, the grantee may request grant funds from PMS monthly on the basis of expected disbursements during the succeeding month and the amount of Federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, a grantee must submit the request through the awarding IC early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment to the grantee electronically through the ACH process upon receipt of the approved payment request from the awarding IC.

## 6.3 INTEREST EARNED ON ADVANCES OF GRANT FUNDS

Except as provided in 45 CFR part 74.22(k), any NIH grantee subject to the requirements of 45 CFR part 74 that receives advance payments must maintain those advances in an interest-bearing account.

Grantees are expected to promptly return any funds not spent within three business days. However, any interest earned on advances of Federal funds must be handled as follows:

- ***Nongovernmental Grantees.*** Any interest on Federal advances of grant funds that exceeds $250 per year in the aggregate must be remitted annually to PMS (as the government-wide agent for collection). Recipients with electronic funds transfer capability should use an electronic medium to remit interest.

- ***Governmental Grantees Other Than States.*** Except as provided in 45 CFR part 92.21(i), any interest in excess of $100 per year in the aggregate earned by local governments or Indian tribal governments on Federal advances of grant funds must be remitted promptly, and at least quarterly, to PMS.

- ***State Governments.*** State governments operating under Treasury-State agreements are subject to the payment and receipt of interest as specified in their agreements. All other State grantees are expected to follow sound financial management practices that minimize the potential for excessive Federal cash on hand and to comply with the cash management requirements of 45 CFR parts 92.20 and 21.

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# 7 COST CONSIDERATIONS

## 7.1 GENERAL

Cost considerations are critical throughout the life cycle of a grant. An applicant's budget request is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of recipient and the type of award. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the grantee may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for grantees to deviate from the award budget, depending on the deviation's significance to the project or activity. More significant post-award changes require NIH prior approval. Prior approval requirements and authorities are discussed in Administrative Requirements—Changes in Project and Budget.

During post-award administration, the GMO, or a GMO designee, monitors expenditures for conformance with cost policies. The GMO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports. The GMO also may use audit findings as the basis for final cost adjustments (see Administrative Requirements—Closeout).

This chapter addresses the general principles underlying the allowability of costs, differentiates direct costs from F&A costs, and highlights a number of specific costs and categories of cost for NIH applicants and grantees. It is not intended to be all-inclusive and should be used as a supplement to the applicable cost principles.

## 7.2 THE COST PRINCIPLES

In general, NIH grant awards provide for reimbursement of actual, allowable costs incurred and are subject to Federal cost principles. The cost principles establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or F&A costs, and set forth allowability and allocability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization (regardless whether domestic or foreign) making the expenditure. For example, a for-profit organization collaborating with a university grantee would be subject to the cost principles for commercial organizations, while the university would be subject to the cost principles for educational institutions.

The cost principles are set forth in the following documents and are incorporated by reference in 45 CFR parts 74.27 and 92.22. As noted below, OMB Circulars A-21, A-87 and A-122 have relocated to Title 2 in the Code of Federal Regulations (2 CFR) :

- OMB Circular A-21 (relocated to 2 CFR part 220) —Cost Principles for Educational Institutions.
- OMB Circular A-87 (relocated to 2 CFR part 225) —Cost Principles for State and Local Governments and Indian Tribal Governments.
- OMB Circular A-122 (relocated to 2 CFR part 230) —Cost Principles for Non-Profit Institutions. Larger non-profit organizations that are specifically listed in Attachment C to OMB Circular A-

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122 are subject to the Federal cost principles applicable to commercial organizations (48 CFR part 31.2) rather than to the cost principles for non-profit organizations.

- 45 CFR part 74, Appendix E —Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals.

- 48 CFR part 31.2 (Federal Acquisition Regulation) —Contracts with Commercial Organizations.

The cost principles apply to all NIH award instruments, award mechanisms, and special programs and authorities, including modular awards and awards under SNAP with one exception: they do not apply to Kirschstein-NRSA individual fellowship awards. The allowable use of funds under those awards is included in Ruth L. Kirschstein National Research Service Awards in IIB.

Grantees may use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as they meet the standards prescribed in 45 CFR part 74.21 or 92.20 for financial management systems.

The cost principles address four tests to determine the allowability of costs. The tests are as follows:

- ***Reasonableness (Including Necessity).*** A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the grant's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large as well as to the organization.

- ***Allocability.*** A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable to a grant if it is incurred solely in order to advance work under the grant; it benefits both the grant and other work of the institution, including other grant-supported projects; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant. A cost is allocable as a direct cost to a grant if it is incurred solely in order to advance work under the grant or meets the criteria for closely related projects determination (see Cost Considerations—Allocation of Costs and Closely Related Work).

- ***Consistency.*** Grantees must be consistent in assigning costs to cost objectives. Costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program, but all costs must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding.

- ***Conformance.*** This test of allowability—conformance with limitations and exclusions as contained in the terms and conditions of award, including those in the cost principles—varies by the type of activity, the type of recipient, and other characteristics of individual awards. Cost Considerations—Allowability of Costs/Activities provides information common to most NIH grants and, where appropriate, specifies some of the distinctions if there is a different treatment based on the type of grant or grantee. IIB contains additional information on allowability of costs for particular types of grants, grantees, and activities.

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These four tests apply regardless of whether the particular category of costs is one specified in the cost principles or one governed by other terms and conditions of an award. These tests also apply regardless of treatment as a direct cost or an F&A cost. The fact that a proposed cost is awarded as requested by an applicant does not indicate a determination of allowability.

## 7.3 DIRECT COSTS AND FACILITIES AND ADMINISTRATIVE COSTS

A direct cost is any cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the grant-supported project or activity. Most organizations also incur costs for common or joint objectives that cannot be readily identified with an individual project, program, or organizational activity. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that usually are treated as F&A costs. The organization is responsible for presenting costs consistently and must not include costs associated with its F&A rate as direct costs.

Note, the term facilities and administrative costs and the term indirect costs may be used interchangeably to determine applicable policies. For NIH purposes, including the NIHGPS, these costs will be referred to as F&A costs; however, other documents or non-NIH entities may refer to them as indirect costs.

Project costs consist of the allowable direct costs directly related to the performance of the grant plus the allocable portion of the allowable F&A costs of the organization, less applicable credits (as described below and in the cost principles).

The amount NIH awards for each budget period will reflect the total approved budget for the grant, including direct costs and, if applicable, F&A costs. (SBIR and STTR awards also may include a fee as specified in Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs in IIB.) If a grantee waives reimbursement of full F&A costs, NIH will either not award F&A costs or will award only partial F&A costs, as appropriate. The NIH award amount shown in the NoA constitutes NIH's maximum financial obligation to the grantee under that award.

## 7.4 REIMBURSEMENT OF FACILITIES AND ADMINISTRATIVE COSTS

For grant programs that can provide F&A cost reimbursement, NIH will generally not provide F&A costs unless the grantee has established an F&A cost rate covering the applicable activities and period of time, except for awards under which F&A costs are reimbursed at a fixed rate.

In addition, NIH will not require a recipient to establish an F&A rate if the organization's total operations consist of a single grant-supported project or if the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such. In the latter case, the GMO must be satisfied that the organization's accounting system can adequately identify and support all costs as direct costs to the project. This includes being able to identify and segregate costs on the basis of a process that assigns costs commensurate with the benefits provided to individual projects (see Administrative Requirements—Management Systems and Procedures—Financial Management System Standards).

F&A rates are negotiated by DCA, DFAS in the Office of Acquisition Management and Policy, NIH (responsible for negotiating F&A cost rates for for-profit entities receiving awards from HHS), or other

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agency with cognizance for F&A cost rate (and other special rate) negotiation. If an applicant is advised by the GMO of the need to establish a rate, the GMO will indicate the responsible office to be contacted. If a grantee does not have a negotiated F&A rate, the use of a temporary F&A rate, such as 10% of salaries and wages (S&W), may be used while a rate agreement is being negotiated.

F&A cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant office or agency, and must conform to cost policies in the NIHGPS. Further information concerning the establishment of F&A rates and the reimbursement of F&A costs may be obtained from DCA or DFAS (see Part III). DCA should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of OMB Circular A-21.

In accordance with NIH's cost management plan, regardless of the type of recipient, the negotiated rate(s) in effect at the beginning of the competitive segment will be used to determine the amount budgeted for F&A costs for each year of the competitive segment. If the rate agreement does not extend to the end of the project period, the last rate in effect will be used to establish the total cost commitment for any remaining future years. NIH generally will not award additional F&A costs beyond those calculated in the approved budget.

F&A costs awarded may be subject to upward or downward adjustment, depending on the type of rate negotiated and grantee type. Generally, grantees may rebudget between direct and F&A costs (in either direction) without NIH prior approval, provided there is no change in the scope of the approved project. F&A cost reimbursement on grants subject to OMB Circular A-21 is based on the rates used in the award, which are not subject to adjustment in reimbursement except for the establishment of permanent rates when a provisional rate was used for funding. Therefore, grantees subject to A-21 may not rebudget from direct costs to accommodate a rate increase if the F&A costs provided for a period were based on negotiated (fixed or predetermined) rates rather than provisional rates (defined as not "negotiated" for the application of the OMB Circular A-21 requirement). However, for non A-21 grantees, F&A cost reimbursement is based on the negotiated F&A rate agreement consistent with the time period when the cost is incurred, except if F&A costs were limited or not provided, SBIR/STTR awardees, and other grantees that have never established a rate. F&A costs are subject to downward adjustment if the proposal that served as the basis for the negotiation included unallowable costs.

Some grants require negotiation of project costs annually, e.g., clinical trials, and Primate Research Center Grants (P51). For these awards, the policies pertain to each year of support rather than to a multiyear competitive segment.

Once NIH awards a grant, it is not obligated to make any supplemental or other award for additional F&A costs or for any other purpose. There are limited circumstances under which the GMO may award F&A costs where none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for F&A costs because the applicant or grantee did not submit a timely F&A cost proposal and the grantee subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for F&A costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the F&A costs applicable to the period after the date of the grantee's F&A cost proposal submission. This provision does not affect local governmental agencies that are not required to submit their F&A (indirect) cost proposals to the Federal government. They may charge F&A costs to NIH grants based on the rate computations they prepare and keep on file for subsequent Federal review.

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If funds are available, a GMO may amend an award to provide additional funds for F&A costs, but only under the following circumstances:

- NIH made an error in computing the award. This includes situations in which a higher rate than the rate used in the grant award is negotiated and the date of the rate agreement for the higher rate is on or before 1 calendar month prior to the beginning date of the grant budget period.

- NIH restores funds previously recaptured as part of a grantee's unobligated balance.

- The grantee is eligible for additional F&A costs associated with additional direct costs awarded for the supplementation or extension of a project.

NIH does not reimburse indirect costs under the following classes of awards:

- ***Fellowships.*** F&A costs will not be provided on Kirschstein-NRSA individual fellowships or similar awards for which NIH funding is in the form of fixed amounts or is determined by the normal published tuition rates of an institution and for which the recipient is not required to account on an actual cost basis.

- ***Construction.*** F&A costs will not be provided on construction grants.

- ***Grants to Individuals.*** F&A costs will not be provided on awards to individuals.

- ***Grants to Federal Institutions.*** F&A costs will not be provided on grants to Federal institutions.

- ***Grants in Support of Scientific Meetings (Conference Grants).*** F&A costs will not be provided under grants in support of scientific meetings.

NIH provides F&A costs without the need for a negotiated rate under the following classes of awards:

- ***Research Training and Education Grants (e.g., R25), and K Awards.*** F&A costs under Kirschstein-NRSA institutional research training grants and K awards will be budgeted and reimbursed at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, health insurance (when awarded as part of tuition and fees), expenditures for equipment, and consortiums in excess of $25,000. State, local, and Indian tribal governmental agencies may receive full F&A cost reimbursement under NIH Kirschstein-NRSA institutional research training grants and K awards. For this policy, State universities or hospitals are not considered governmental agencies.

- ***Grants to Foreign Institutions and International Organizations.*** With the exception of the American University of Beirut and the World Health Organization, which are eligible for full F&A cost reimbursement, F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of modified total direct costs, exclusive of expenditures for equipment. NIH provides F&A costs under these grants to support the costs of compliance with applicable public policy requirements including, but not limited to, the protection of human subjects, animal welfare, financial conflict of interest, and invention reporting. NIH will not support the acquisition of or provide for depreciation on any capital expenses (facilities) or the normal general operations of foreign and international organizations. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, less equipment, for the consortium.

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## 7.5 COST TRANSFERS, OVERRUNS, AND ACCELERATED AND DELAYED EXPENDITURES

Cost transfers to NIH grants by grantees, consortium participants, or contractors under grants that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the grantee, consortium participant, or contractor. An explanation merely stating that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.

Grantees must maintain documentation of cost transfers, pursuant to 45 CFR part 74.53 or 92.42, and must make it available for audit or other review (see Administrative Requirements—Monitoring—Record Retention and Access). The grantee should have systems in place to detect such errors within a reasonable time frame; untimely discovery of errors could be an indication of poor internal controls. Frequent errors in recording costs may indicate the need for accounting system improvements, enhanced internal controls, or both. If such errors occur, grantees are encouraged to evaluate the need for improvements and to make whatever improvements are deemed necessary to prevent reoccurrence. NIH also may require a grantee to take corrective action by imposing additional terms and conditions on an award(s).

The GMO monitors grantee expenditure rates under individual grants within each budget period and within the overall project period. The funding that NIH provides for each budget period is based on an assessment of the effort to be performed during that period and the grantee's associated budget, including the availability of unobligated balances. Although NIH allows grantees certain flexibilities with respect to rebudgeting (see Administrative Requirements—Changes in Project and Budget), NIH expects the rate and types of expenditures to be consistent with the approved project and budget and may question or restrict expenditures that appear inconsistent with these expectations.

The GMO may review grantee cash drawdowns to determine whether they indicate any pattern of accelerated or delayed expenditures. Expenditure patterns are of particular concern because they may indicate a deficiency in the grantee's financial management system or internal controls. Accelerated or delayed expenditures may result in a grantee's inability to complete the approved project within the approved budget and period of performance. In these situations, the GMO may seek additional information from the grantee and may make any necessary and appropriate adjustments.

## 7.6 ALLOCATION OF COSTS AND CLOSELY RELATED WORK

When salaries or other activities are supported by two or more sources, issues arise as to how the direct costs should be allocated among the sources of support. In general, a cost that benefits two or more projects or activities in proportions that can be determined without undue effort or cost should be allocated to the projects on the basis of the proportional benefit. A cost that benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved may be allocated or transferred to the benefiting projects on any reasonable basis as long as the costs charged are allowable, allocable, and reasonable under the applicable cost principles and the grantee's financial management system includes adequate internal controls (for example, no one person has complete control over all aspects of a financial transaction). As a result, a grantee may allocate costs normally assignable to multiple projects to one of those projects.

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## 7.7 APPLICABLE CREDITS

The term applicable credits refers to those receipt or negative expenditure types of transactions that operate to offset or reduce direct or F&A cost items. Typical examples are purchase discounts, rebates or allowances, recoveries or indemnities on losses, and adjustments for overpayments or erroneous charges. Additional information concerning applicable credits is included in the cost principles.

Applicable credits to direct charges made to NIH grants must be treated as an adjustment on the grantee's FFR, whether those credits accrue during or after the period of grant support. (See Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout—Final Federal Financial Reports.) The NIH awarding IC will notify the grantee of any additional actions that may be necessary.

## 7.8 SERVICES PROVIDED BY AFFILIATED ORGANIZATIONS

A number of universities and other organizations have established closely affiliated, but separately incorporated, organizations to facilitate the administration of research and other programs supported by Federal funds. Such legally independent entities are often referred to as "foundations," although this term does not necessarily appear in the name of the organization. Sometimes, the parent organization provides considerable support services, in the form of administration, facilities, equipment, accounting, and other services, to its foundation, and the latter, acting in its own right as an NIH grantee, includes the cost of these services in its F&A proposal.

Costs incurred by an affiliated, but separate, legal entity in support of a grantee foundation are allowable for reimbursement under NIH grants only if at least one of the following conditions is met:

- The affiliated organization is charged for, and is legally obligated to pay for, the services provided by the parent organization.
- The affiliated organizations are subject to State or local law that prescribes how Federal reimbursement for the costs of the parent organization's services will be expended and requires that a State or local official acting in his or her official capacity approves such expenditures.
- There is a valid written agreement between the affiliated organizations whereby the parent organization agrees that the grantee foundation may retain Federal reimbursement of parent organization costs. The parent organization may either direct how the funds will be used or permit the grantee foundation that discretion.

If none of the above conditions are met, the costs of the services provided by the parent organization to the grantee foundation are not allowable for reimbursement under an NIH grant. However, the services may be acceptable for cost-sharing (matching) purposes.

Foundations that represent already existing grantee organizations should contact DGP, OPERA before attempting to become a separately recognized applicant organization.

## 7.9 ALLOWABILITY OF COSTS/ACTIVITIES

The governing cost principles address selected items of cost, some of which are mentioned in this section for emphasis. This section is not intended to be all-inclusive. The cost principles should be consulted for the complete explanation of the allowability or unallowability of costs.

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This section also includes NIH-specific requirements concerning costs and activities. The allowability of costs under specific NIH awards may be subject to other requirements specified in the program legislation, regulations, or the specific terms and conditions of an award, which take precedence over the general discussion provided here. Specific program requirement may also be covered in other sections of the NIH GPS. Applicants or grantees that have questions concerning the allowability of particular costs should contact the GMO.

If a cost is allowable, it is allocable as either a direct cost or an F&A cost, depending on the grantee's accounting system. For some costs addressed in this section, the text specifies whether the cost is usually a direct cost or an F&A cost.

Unless otherwise indicated in the NoA, an award based on an application that includes specific information concerning any costs or activities that require NIH prior approval constitutes the prior approval for those costs or activities. The grantee is not required to obtain any additional approval for those costs/activities. Post-award requests to incur costs or undertake activities requiring prior approval that are not described in the approved application are subject to the requirements in Administrative Requirements—Changes in Project and Budget.

Consortium participants and contractors under grants are subject to the requirements of the cost principles otherwise applicable to their type of organization and to any requirements placed on them by the grantee to be able to comply with the terms and conditions of the NIH grant.

The cost principles do not address profit or fee. NIH policy allows the payment of fee on SBIR/STTR grants (see Grants to For-Profit Organizations chapter in IIB) but NIH will not provide profit or fee to any other type of recipient under any other grant program or support mechanism. A fee may not be paid by a grantee to a consortium participant, including a for-profit organization. However, a fee (profit) may be paid to a contractor providing routine goods or services under a grant in accordance with normal commercial practice.

## 7.9.1 Selected Items of Cost

**Exhibit 5: Selected Items of Cost**

The table presents specific items that may or may not be included in the cost portion of grants.

| Items | Explanation of Allowable Costs |
|---|---|
| Advertising | Allowable only for recruitment of staff, trainees, or study participants; procurement of goods and services; disposal of scrap or surplus materials; and, other specific purposes necessary to meet the requirements of the grant-supported project or activity. |
| Alcoholic Beverages | Unallowable as an entertainment expense, but allowable if within the scope of an approved research project. |
| Alteration and Renovation | Individual A&R projects that are treated as direct costs and that will not exceed $500,000 will be subject to the A&R policies specified in this exhibit and in the Construction Grants chapter, as applicable. Individual A&R projects exceeding $500,000 in direct costs will be subject to the requirements specified in the Construction Grants chapter.<br><br>Routine maintenance and repair of the organization's physical plant or equipment, |

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| Items | Explanation of Allowable Costs |
|---|---|
| | which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this policy. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, may be considered either equipment costs or A&R costs, depending on the grantee's accounting system.<br><br>A&R costs are not allowable under grants to individuals, and grants in support of scientific meetings (conference grants). In all other cases, these costs are allowable unless the program legislation, implementing regulations, program guidelines, or other terms and conditions of the award specifically exclude such activity.<br><br>The A&R must be consistent with the following criteria and documentation requirements:<br><br>• The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required.<br>• The A&R is essential to the purpose of the grant-supported project.<br>• The space involved will be occupied by the project.<br>• The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage.<br>• If the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the project period.<br>• If the A&R will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the requirements specified in "Preservation of Cultural and Historic Resources" have been followed.<br><br>Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost.<br><br>A grantee may rebudget up to 25 percent of the total approved budget for a budget period into A&R costs without NIH prior approval unless such rebudgeting would result in a change in scope. If the rebudgeting results in an A&R project exceeding $300,000, NIH will consider the rebudgeting to be a change in scope, and the grantee must submit to the NIH awarding IC the documentation specified in the Construction Grants chapter for approval of A&R projects above that dollar level.<br><br>Under foreign grants or foreign components under domestic grants, major A&R (>$500,000) is unallowable. Minor A&R (<$500,000) is generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations. |

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| Items | Explanation of Allowable Costs |
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| Animals | Allowable for the acquisition, care, and use of experimental animals, contingent upon compliance with the applicable requirements of the *PHS Policy on Humane Care and Use of Laboratory Animals* (see Public Policy Requirements and Objectives—Animal Welfare). If the grantee operates an animal resource facility, charges for use of the facility should be determined in accordance with the *Cost Analysis and Rate Setting Manual for Animal Resource Facilities* (May 2000), available from NCRR at its Web site: (http://www.ncrr.nih.gov/publications/comparative_medicine/CARS.pdf) or from NCRR's Office of Science Policy and Public Liaison (telephone: 301-435-0888; e-mail: infor@ncrr.nih.gov. |
| Audiovisual Activities | Allowable for the production of an audiovisual. "Audiovisual" means any product containing visual imagery, sound, or both, such as motion pictures, films, videotapes, live or recorded radio or television programs or public service announcements, slide shows, filmstrips, audio recordings, multimedia presentations, or exhibits where visual imagery, sound, or both are an integral part. "Production" refers to the steps and techniques used to create a finished audiovisual product including, but not limited to, design, layout, scriptwriting, filming or taping, fabrication, sound recording, and editing.<br><br>A recipient with in-house production capability must determine whether it would be more efficient and economical to use that capability or to contract for the production of an audiovisual.<br><br>If an audiovisual intended for members of the general public (i.e., people who are not researchers or health professions personnel or who are not directly involved in project activities as employees, trainees, or participants such as volunteers or patients) is produced under an NIH grant-supported project, the grantee must submit two copies of the finished product along with its annual or final progress report (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout). The costs of such copies are allowable project costs.<br><br>Audiovisuals produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, such as the following:<br><br>The production of this [type of audiovisual (motion picture, television program, etc.)] was supported by Grant No._____ from [name of NIH awarding IC]. Its contents are solely the responsibility of [name of grantee organization] and do not necessarily represent the official views of [name of NIH awarding IC]. |
| Audit Costs | Allowable (see Administrative Requirements—Monitoring—Audit and section 230 of OMB Circular A-133). The charges may be treated as a direct cost when the audit's scope is limited to a single NIH grant-supported project or program, as specified in 45 CFR part 74.26(d), or when it includes more than one project but the costs can be specifically identified with, and allocated to, each project on a proportional basis, and this practice is followed consistently by the grantee. Otherwise, charges for audits should be treated as F&A costs. |
| Bad Debts | Unallowable. |
| Bid and Contract Proposal Costs | Allowable as an F&A cost. See 45 CFR part 74.27(b)(1) for policy for non-profit organizations covered by OMB Circular A-122. |

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| Items | Explanation of Allowable Costs |
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| Bonding | Allowable. See 45 CFR parts 74.21, 74.47(c) and 92.36 for policies and requirements concerning bonding. |
| Books and Journals | Allowable. If an organization has a library, books and journals generally should be provided as part of normal library services and treated as F&A costs. |
| Building Acquisition | Unallowable unless building acquisition or construction is specifically authorized by program legislation and is provided for in the NoA. For real property acquired with NIH grant support, the cost of title insurance may be charged to the grant in proportion to the Federal share of the acquisition cost. Filing fees for recording the Federal interest in the real property in appropriate records of the applicable jurisdiction also may be charged to the grant. (Also see Construction Grants—Allowable and Unallowable Costs and Activities in IIB.) |
| Child Care Costs | Allowable if incurred to assist individuals to participate as subjects in research projects. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see Fringe Benefits in this exhibit). |
| Communications | Allowable. Such costs include local and long-distance telephone calls, telegrams, express mail, and postage, and usually are treated as F&A costs. |
| Conference Grant Costs | See Support of Scientific Meetings (Conference Grants) chapter in IIB for allowability of costs for scientific meetings (conferences). |
| Consortium Agreements/ Contracts under Grants | Allowable to carry out a portion of the programmatic effort or for the acquisition of routine goods or services under the grant. Such arrangements may require NIH approval as specified in Administrative Requirements—Changes in Project and Budget. (See also Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for policies that apply to the acquisition of routine goods and services and the Consortium Agreements chapter in IIB for policies that apply to grantee collaboration with other organizations in carrying out the grant-supported research.) |
| Construction | Allowable only when program legislation specifically authorizes new construction, modernization, or major A&R, and NIH specifically authorizes such costs in the NoA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy (see Construction Grants chapter in IIB). |
| Consultant Services | Allowable. A consultant is an individual retained to provide professional advice or services for a fee but usually not as an employee of the requiring organization. The term consultant also includes a firm that provides paid professional advice or services. Grantees must have written policies governing their use of consultants that are consistently applied regardless of the source of support. Such policies should include the conditions for paying consulting fees. The general circumstances of allowability of these costs, which may include fees and travel and subsistence costs, are addressed in the applicable cost principles under “professional services costs.”<br><br>In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee as long as those separate services are not related to the same project and are not charged to the same project. For example, consulting fees that are paid by an educational institution to a salaried faculty member as extra |

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| Items | Explanation of Allowable Costs |
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| | compensation above that individual's base salary are allowable, provided the consultation is across departmental lines or involves a separate or remote operation and the work performed by the consultant is in addition to his or her regular departmental workload.<br><br>Grantees, consortium participants, and contractors under grants that want to be able to charge employee consulting costs to grant-supported projects must establish written guidelines permitting such payments regardless of the source of funding and indicating the conditions under which the payment of consulting fees to employees is proper. Unless subject to OMB Circular A-21, the grantee, consortium participant, or contractor also must document that it would be inappropriate or infeasible to compensate the individual for those services through payment of additional salary. Under no circumstances may an individual be paid as a consultant and an employee under the same NIH grant.<br><br>Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be documented in writing, on a case-by-case basis, by the head of the organization (or his/her designee) incurring the costs – i.e., the recipient organization, consortium participant, or contractor. If the designee is personally involved in the project, the authorization may be given only by the head of the recipient organization, consortium participant, or contractor. This authorization must include a determination that the required conditions are present and that there is no apparent or actual conflict of interest.<br><br>Grantees, consortium participants, and contractors under grants are encouraged to obtain written reports from consultants unless such a report is not feasible given the nature of the consultation or would not be useful. Documentation maintained by the receiving organization should include the name of the consulting firm or individual consultant; the nature of the services rendered and their relevance to the grant-supported activities, if not otherwise apparent from the nature of the services; the period of service; the basis for calculating the fee paid (e.g., rate per day or hour worked or rate per unit of service rendered); and the amount paid. This information may be included in the consultant's invoice, in the report, or in another document.<br><br>See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter in IIB for allowable costs associated with consultant payments to Federal employees and the circumstances of allowability. |
| Contingency Funds | Unallowable. Contributions set aside for events whose occurrence cannot be foretold with certainty as to time, intensity, or assurance of their happening are unallowable under non-construction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see Reserve Funds in this exhibit). (See also Construction Grants—Allowable and Unallowable Costs and Activities in IIB concerning contingency funds under construction grants.) |

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| Items | Explanation of Allowable Costs |
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| Customs and Import Duties | Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. Consular fees, customs surtaxes, value-added taxes and other related charges are unallowable on foreign grants or the foreign component of a domestic grant. (See also Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components—Allowable and Unallowable Costs in IIB for the allowability of these costs.) |
| Depreciation or Use Allowances | Allowable. Such costs usually are treated as F&A costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable. |
| Donor Costs | Allowable as payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related. Donor costs are not considered a research patient care expense (see the Research Patient Care Costs chapter in IIB). Also see Incentive Costs in this exhibit. |
| Drugs | Allowable if within the scope of an approved research project.<br><br>Project funds may not be used to purchase drugs classified by FDA as “ineffective” or “possibly effective” except in approved clinical research projects or in cases where there is no alternative other than therapy with “possibly effective” drugs. |
| Dues or Membership Fees | Allowable as an F&A cost for organizational membership in business, professional, or technical organizations or societies.<br><br>Payment of dues or membership fees for an individual’s membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds. |
| Entertainment Costs | Unallowable. This includes the cost of amusements, social activities, and related incidental costs. |
| Equipment | Allowable for purchase of new, used, or replacement equipment as a direct cost or as part of F&A costs, depending on the intended use of the equipment. NIH prior approval may be required as specified in Administrative Requirements—Changes in Project and Budget.<br><br>Office equipment (copiers, laptops, desktop computers, personal handheld computers, fax machines, scanners, etc.) that is used for general office purposes (rather than justified as a specific research purpose) are not allowable as direct costs; they are allowable as an F&A cost.<br><br>Funds provided under a conference grant may not be used to purchase equipment.<br><br>For policies governing the classification, use, management, and disposition of equipment, see Administrative Requirements—Management Systems and Procedures—Property Management System Standards. For policies governing the allowability of costs for rental equipment, see Rental or Lease of Facilities and Equipment in this exhibit. |

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| Items | Explanation of Allowable Costs |
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| Federal (U.S. Government) Employees | See Grants to Federal Institutions and Payments to Federal Employees under Grants—Allowable and Unallowable Costs in IIB for the allowability of payments made to, or on behalf of, Federal employees under NIH grants, including grants to Federal institutions. |
| Fines and Penalties | Unallowable except when resulting from violations of, or failure of the organization to comply with, Federal, State, or local laws and regulations and incurred as a result of compliance with specific provisions of an award, or when such payments are authorized in advance in writing by the NIH awarding IC. |
| Fringe Benefits | Allowable as part of overall compensation to employees in proportion to the amount of time or effort employees devote to the grant-supported project, provided such costs are incurred under formally established and consistently applied policies of the organization (see Salaries and Wages in this exhibit).<br><br>Tuition or tuition remission for regular employees is allowable as a fringe benefit. For organizations subject to OMB Circular A-21, tuition benefits for family members other than the employee are unallowable. For policies applicable to tuition remission for students working on grant-supported research projects, see Salaries and Wages/Compensation of Students in this exhibit. See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Allowable and Unallowable Costs—Tuition and Fees and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs—Trainee Tuition and Fees in IIB for the allowability of tuition costs for fellows and trainees. |
| Fundraising Costs | Unallowable. |
| Hazardous Waste Disposal | Allowable; usually treated as an F&A cost. |
| Honoraria | Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable. |
| Hospitalization | See Research Patient Care in this exhibit. |
| Incentive Costs | Incentive payments to volunteers or patients participating in a grant-supported project or program are allowable. Incentive payments to individuals to motivate them to take advantage of grant-supported health care or other services are allowable if within the scope of an approved project. See Salaries and Wages/Bonus Funds & Incentives in this exhibit for incentive payments to employees. |
| Indemnification | Absent express statutory authority, unallowable if the indemnification would result in liability that is indefinite, indeterminate or potentially unlimited. In those rare cases where authority does allow this cost, it would be reflected in the NoA. |
| Independent Research and Development Costs | Unallowable, including their proportionate share of F&A costs. |

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| Items | Explanation of Allowable Costs |
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| Insurance | Allowable. Insurance usually is treated as an F&A cost. In certain situations, however, where special insurance is required as a condition of the grant because of risks peculiar to the project, the premium may be charged as a direct cost if doing so is consistent with organizational policy. Medical liability (malpractice) insurance is an allowable cost of research programs at educational institutions only if the research involves human subjects. If so, the insurance should be treated as a direct cost and assigned to individual grants based on the manner in which the insurer allocates the risk to the population covered by the insurance.<br><br>The cost of insuring equipment, whether purchased with project funds or furnished as federally owned property, normally should be included in F&A costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy.<br><br>Health insurance for trainees and fellows is addressed in the Ruth L. Kirschstein National Research Service Awards chapter in IIB. |
| Interest | Allowable as an F&A cost for certain assets as specified in the applicable cost principles. Unallowable for hospitals (see Payment—Interest Earned on Advances of Grant Funds). |
| Invention, Copyright, Patent, or Licensing Costs | Unallowable as a direct cost unless specifically authorized on the grant award. May be allowable as F&A costs, provided they are authorized under applicable cost principles and are included in the negotiation of F&A cost rates. Such costs include licensing or option fees, attorney's fees for preparing or submitting patent application, patent maintenance, or recordation of patent-related information. |
| IRB or IACUC Costs | Costs associated with IRB review of human research protocols, or IACUC review of animal research protocols, are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate. |
| Laboratory Directed Research & Development | NIH awards to DOE laboratories will not include the proportionate share of F&A costs for Laboratory Directed Research & Development (LDRD) in accordance with the MOU with the Department of Energy dated June 18, 1998, although the NIH will not restrict the DOE laboratory contractors from recovering LDRD costs within the total funding included in an award. In addition, DOE has agreed to waive the Overhead Rate on all NIH grant awards to DOE laboratory contractors. |
| Leave | Allowable for employees as a fringe benefit (see Fringe Benefits in this exhibit). See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Other Terms and Conditions—Leave and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Other Terms and Conditions—Leave in IIB for NIH policy on leave for fellows and trainees. |
| Legal Services | Allowable. Generally treated as an F&A cost but, subject to the limitations described in the applicable cost principles, may be treated as a direct cost for legal services provided by individuals who are not employees of the grantee organization. Before a grantee incurs legal costs that are extraordinary or unusual in nature, the grantee should make an advance agreement regarding the appropriateness and reasonableness of such costs with the GMO.<br><br>Legal costs incurred in defending or prosecuting claims, whether equitable or monetary, including administrative grant appeals, are unallowable charges to NIH grant-supported projects, except as provided in the applicable cost principles. |

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| Items | Explanation of Allowable Costs |
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| Library Services | General library support is not allowable as a direct cost but may be included in the grantee's F&A pool. However, such services are allowable as a direct cost when specifically required for the conduct of the project and when identifiable as an integral part of the grant-supported activity (e.g., in those programs designed to develop and support such services). |
| Lobbying | Generally unallowable, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a State legislature. Under certain circumstances, as provided in the applicable cost principles, costs associated with activities that might otherwise be considered "lobbying" that are directly related to the performance of a grant may be allowable. The grantee should obtain an advance understanding with the GMO if it intends to engage in these activities. Unallowable for State and Local governments and for-profit organizations. (Also see Public Policy Requirements and Objectives—Lobbying Prohibition, Appropriation Mandates – Lobbying – Appropriation Prohibition, and Administrative Requirements—Monitoring—Reporting concerning lobbying restrictions, the required certification, and reporting.) |
| Maintenance and Repair Costs | Costs incurred for necessary maintenance, repair or upkeep of buildings and equipment (including Federal property unless otherwise provided for) which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are allowable. Costs incurred for improvements which add to the permanent value of the buildings and equipment or appreciably prolong their intended life shall be treated as capital expenditures. |
| Meals | Allowable for subjects and patients under study, or where specifically approved as part of the project activity, provided that such charges are not duplicated in participants' per diem or subsistence allowances, if any.<br><br>When certain meals are an integral and necessary part of a meeting or conference (i.e., a working meal where business is transacted), grant funds may be used for such meals. The cost of meals served at a meeting or conference, for which the primary purpose is the dissemination of technical information, is allowable. In all cases the cost of any meal must meet a test of reasonableness. However, recurring business meetings, such as staff meetings, should not be broadly considered as meetings for the primary purpose of disseminating technical information in order to justify charging meals or refreshment to costs to grants. |
| Moving | See Recruitment Costs, Relocation Costs, and Transportation of Property in this exhibit. |
| Nursery Items | Allowable for the purchase of items such as toys and games to allow patients to participate in research protocols. |
| Overtime | See Salaries and Wages/Overtime Premiums in this exhibit. |

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| Items | Explanation of Allowable Costs |
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| Pension Plan Costs | Allowable. For institutions of higher education and non-profit organizations, such costs must be incurred according to the established policies of the organization consistently applied regardless of the source of funds, the organization's policies must meet the test of reasonableness, the methods of cost allocation must be equitable for all activities, the amount assigned to each fiscal year must be determined in accordance with generally accepted accounting principles, and the cost assigned to a given fiscal year must be paid or funded for all plan participants within 6 months after the end of that fiscal year.<br><br>State, local, or Indian tribal governments or hospitals may use the "pay-as-you-go" cost method (i.e., when pension benefits are paid by the grantee directly to, or on behalf of, retired employees or their beneficiaries) in lieu of the method described above. Under this method, the benefits may be charged in the grantee's fiscal year in which the payments are made to, or on behalf of, retired employees or their beneficiaries, provided that the grantee follows a consistent policy of treating such payments as expenses in the year of payment. See the applicable cost principles for additional information on the allowability of costs associated with pension plans. |
| Pre-Award (Pre-Agreement) Costs | Allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs:<br><br>• are necessary to conduct the project, and<br>• would be allowable under the grant, if awarded, without NIH prior approval.<br><br>If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.<br><br>Grantees may incur pre-award costs before the beginning date of a non-competing continuation award without regard to the time parameters stated above.<br><br>The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred.<br><br>NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project.<br><br>Pre-Award Costs are generally not applicable to training grants or fellowships. See respective sections for Individual Fellowships and Institutional Training Grants in the Ruth L. Kirschstein National Research Service Award chapter in IIB for additional information. |

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| Items | Explanation of Allowable Costs |
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| 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. |
| Public Relations Costs | Allowable only for costs specifically required by the award or for costs of communicating with the public and the press about specific activities or accomplishments under the grant-supported project or other appropriate matters of public concern. Such costs may be treated as direct costs but should be treated as F&A costs if they benefit more than one sponsored agreement or if they benefit the grant and other work of the organization. |
| Publications | Allowable. Charges for publication in professional journals, including author fees, are allowable if such costs are actual, allowable, and reasonable to advance the objectives of the award; are charged consistently (by the journal) regardless of the source of support; and all other applicable rules on allowability of costs are met.<br><br>The costs of reprints and publishing in other media, such as books, monographs, and pamphlets, also are allowable.<br><br>Publications and journal articles produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, as appropriate, as provided in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources. |
| Recruitment Costs | Allowable subject to the conditions and restrictions contained in the applicable cost principles. These costs may include help-wanted advertising costs, costs of travel by applicants to and from preemployment interviews, and travel costs of employees while engaged in recruiting personnel. Visa costs are an allowable direct cost as part of recruiting costs as long as the institution has an employee/employer relationship with the individual. Project funds may not be used for a prospective trainee's travel costs to or from the grantee organization for the purpose of recruitment. However, other costs incurred in connection with recruitment under training programs, such as advertising, may be allocated to a grant-supported project according to the provisions of the applicable cost principles (also see Travel, Relocation Costs, and Visa Costs in this exhibit). |
| Registration Fees (for Symposiums and Seminars) | Allowable if necessary to accomplish project objectives. |
| Relocation Costs | Allowable—in other than change of grantee organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the grantee's benefit rather than the individual's and that payment is made according to established organizational policies consistently applied regardless of the source of funds. Relocation costs may include the cost of transporting the employee and his or her family, dependents, and household goods to the new location and certain expenses associated with the sale of the former home. If relocation costs have been incurred in connection with the |

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| | recruitment of a new employee, whether as a direct cost or an F&A cost, and the employee resigns for reasons within his or her control within 12 months after hire, the grantee must credit the grant account for the full cost of the relocation charged to the grant.<br><br>When there is a change in the grantee organization, the personal relocation expenses of the PD/PI and others moving from the original grantee to the new grantee are not allowable charges to NIH grants (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements). |
| Rental or Lease of Facilities and Equipment | Allowable subject to the limitations below. Rental costs are allowable to the extent that the rates are reasonable at the time of the decision to lease in light of such factors as rental costs of comparable property, if any; market conditions in the area; the type, life expectancy, condition, and value of the property leased; and available alternatives. Because of the complexity involved in determining the allowable amount under certain types of leases, grantees are encouraged to consult the GMO before entering into leases that will result in direct charges to the grant project.<br><br>In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. However, see Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for an exception to this general rule.<br><br>Rental costs under leases that create a material equity in the leased property, as defined in the applicable cost principles, are allowable only up to the amount that would be allowed had the grantee purchased the property on the date the lease agreement was executed. This would include depreciation or use allowances, maintenance, taxes, and insurance, but would exclude unallowable costs.<br><br>When a grantee transfers property to a third party through sale, lease, or otherwise, and then leases the property back from that third party, the lease costs that may be charged to NIH projects generally may not exceed the amount that would be allowed if the grantee continued to own the property.<br><br>Rental costs under “less-than-arms-length” leases are allowable only up to the amount that would be allowed under the applicable cost principles had title to the property been vested in the grantee. A less-than-arms-length lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest. |
| Research Patient Care | The costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers, participating in research programs are allowable. Incurrence of patient care costs if not previously approved by NIH and rebudgeting additional funds into, or rebudgeting approved amounts out of, the research patient care costs category may be considered a change in scope and require prior approval by the NIH awarding IC. |

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| | Routine services include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made. Ancillary services are those special services for which charges customarily are made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology. See the Research Patient Care Costs chapter in IIB for NIH policy concerning reimbursement of these costs.<br><br>The following otherwise allowable costs are not classified as research patient care costs: items of personal expense such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors. Such costs should be included in the "Other Expenses" category of the grant budget. |
| Reserve Funds | Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see Contingency Funds in this exhibit). |
| Sabbatical Leave Costs | Sabbatical leave costs may be included in a fringe benefit rate or in the organization's F&A rate. Salary may be charged directly to a project for services rendered to the project by individuals while they are on sabbatical leave, provided the salary is proportional to the service rendered and is paid according to established organizational policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of that individual's regular salary from his or her organization. |
| Salaries and Wages | Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project. Compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reasonably reflect the percentage of time actually devoted to the NIH-funded project. Direct salary is exclusive of fringe benefits and F&A costs. This salary guidance does not apply to consultant payments or to contracts for routine goods and services but it does apply to consortium participants (see the Consortium Agreements chapter in IIB). Salaries of federal employees with permanent appointments are unallowable except in certain circumstances (see the Grants to Federal Institutions and Payments to Federal Employees Under Grants chapter in IIB). |
| Salaries and Wages / *Payroll Distribution* | Salary and wage amounts charged to grant-supported projects for personal services must be based on an adequate payroll distribution system that documents such distribution in accordance with applicable Federal Cost Principles and consistently applied institutional policy and practices. |
| Salaries and Wages / *Overtime Premiums* | Premiums for overtime generally are allowable; however, such payments are not allowable for faculty members at institutions of higher education. If overtime premiums are allowable, the categories or classifications of employees eligible to receive overtime premiums should be determined according to the formally established policies of the organization consistently applied regardless of the source of funds. |

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| Items | Explanation of Allowable Costs |
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| Salaries and Wages / *Bonus Funds & Incentive Payments* | Allowable as part of a total compensation package, provided such payments are reasonable and are made according to a formally established policy of the grantee that is consistently applied regardless of the source of funds. |
| Salaries and Wages / *Payments for Dual Appointments* | For investigators receiving compensation from the institution (grantee/contractor) and separately organized clinical practice plans, compensation from such sources may be included in the institutional base salary (IBS) budgeted and charged to NIH sponsored agreements if all of the following criteria are met:<br>• Clinical practice compensation must be set by the institution. *<br>• Clinical practice activity must be shown on the institution's payroll or salary appointment forms and records approved by the institution.<br>• Clinical practice compensation must be paid through or at the direction of the institution.<br>• Clinical practice activity must be included and accounted for in the institution's effort reporting and/or payroll distribution system.<br>• The institution must assure that all financial reports and supporting documents associated with the combined IBS and resulting charges to NIH grants are retained and made available to Federal officials or their duly authorized representatives consistent with the requirements of 45 CFR part 74.53 (A-110 Subpart C 53).<br>* "Set by the institution" means the grantee/contractor institution must be in a position to document and certify that the specified amount of clinical practice compensation is being paid in essentially the same manner as other specified amounts of the committed IBS (compensation) of the investigator. Further, this requires that the IBS not vary based on the specific clinical services provided by investigator within the periods for which total IBS is certified by the grantee institution. |
| Salaries and Wages / *Support from Multiple Grants* | See Cost Considerations—Allocation of Costs and Closely Related Work. |
| Salaries and Wages / *Compensation of Students* | Tuition remission and other forms of compensation paid as, or in lieu of, wages to students (including fellows and trainees) under research grants are allowable, provided the following conditions are met:<br>• The individual is performing activities necessary to the grant<br>• Tuition remission and other forms of compensation are consistently provided, in accordance with established institutional policy, to students performing similar activities conducted in nonsponsored as well as in sponsored activities<br>• During the academic period, the student is enrolled in an advanced degree program at a grantee or affiliated institution and the activities of the student in relation to the federally sponsored research project are related to the degree program.<br>Charges for tuition remission and other forms of compensation paid to students as, or |

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| Items | Explanation of Allowable Costs |
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| | in lieu of, salaries and wages are subject to the reporting requirements in section J.8. of OMB Circular A-21, or an equivalent method for documenting the individual's effort on the research project. Tuition remission may be charged on an average rate basis. NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of OMB Circular A-21 and its current operating guidelines.<br><br>The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is the zero-level Kirschstein-NRSA stipend in effect when NIH issues the grant award (see current levels posted at http://grants.nih.gov/training/nrsa.htm).<br><br>Payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project. |
| Service Charges | Allowable. The costs to a user of organizational services and central facilities owned by the grantee organization, such as central laboratory, technology infrastructure fees, computer services and next generation computing/communication costs, are allowable provided that they are not covered by F&A costs. They must be based on organizational fee schedules consistently applied regardless of the source of funds. |
| Severance Pay | Allowable only to the extent that such payments are required by law, are included in an employer-employee agreement, are part of an established policy effectively constituting an implied agreement on the part of the organization, or meet the circumstances of the particular employment. The amount of severance pay to be provided should be determined according to established organizational policy consistently applied regardless of the source of funds and should be reasonable, taking into consideration the practice of similar types of organizations and the extent of the organization's dependence on Federal funds. The applicable cost principles should be consulted regarding the different treatment of severance pay in regular and mass termination situations. |
| Stipends | Allowable as cost-of-living allowances for trainees and fellows only under Kirschstein-NRSA individual fellowships and institutional research training grants. These payments are made according to a preestablished schedule based on the individual's experience and level of training. A stipend is not a fee-for-service payment and is not subject to the cost accounting requirements of the cost principles. Additional information, including NIH policy on stipend supplementation, is included in Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Supplementation of Stipends, Compensation, and Other Income—Stipend Supplementation and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Stipend Supplementation, Compensation, and Other Income—Stipend Supplementation in IIB. Stipends are not allowable under research grants even when they appear to benefit the research project. See Salary and Wages/Compensation of Students in this exhibit. |
| Subject Costs | See Research Patient Care and Donor Costs in this exhibit. |
| Supplies | Allowable. |

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| Items | Explanation of Allowable Costs |
|---|---|
| Taxes | Allowable. Such costs include taxes that an organization is required to pay as they relate to employment, services, travel, rental, or purchasing for a project. Grantees must avail themselves of any tax exemptions for which activities supported by Federal funds may qualify. State sales and use taxes for materials and equipment are allowable only when the State does not grant a refund or exemption on such taxes. |
| Termination or Suspension Costs | Unallowable except as follows. If a grant is terminated or suspended, the grantee may not incur new obligations after the effective date of the termination or suspension and must cancel as many outstanding obligations as possible (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support). NIH will allow full credit to the grantee for the Federal share of otherwise allowable costs if the obligations were properly incurred by the grantee before suspension or termination—and not in anticipation of it—and, in the case of termination, are not cancelable. The GMO may authorize other costs in, or subsequent to, the notice of termination or suspension. See 45 CFR parts 74.62(c) and 92.43. |
| Trailers and Modular Units | Allowable only if considered equipment as provided below. A "trailer" is defined as a portable vehicle built on a chassis that is designed to be hauled from one site to another by a separate means of propulsion and that serves, wherever parked, as a dwelling or place of business. A "modular unit" is a prefabricated portable unit designed to be moved to a site and assembled on a foundation to serve as a dwelling or a place of business. The determination of whether costs to acquire trailers or modular units are allowable charges to NIH grant-supported projects depends on whether such units are classified as real property or equipment. The classification will depend on whether the grantee's intended use of the property is permanent or temporary.<br><br>A trailer or modular unit is considered real property when the unit and its installation are designed or planned to be installed permanently at a given location so as to seem fixed to the land as a permanent structure or appurtenance thereto. Units classified as real property may not be charged to an NIH grant-supported project unless authorizing legislation permits construction or acquisition of real property and the specific purchase is approved by the NIH awarding IC.<br><br>A trailer or modular unit is considered equipment when the unit and its installation are designed or planned to be used at any given location for a limited time only. Units classified as equipment may be charged to NIH grant-supported projects only if the terms and conditions of the award do not prohibit the purchase of equipment and NIH prior approval is obtained, as appropriate.<br><br>A trailer or modular unit properly classified as real property or as equipment at the time of acquisition retains that classification for the life of the item, thereby determining the appropriate accountability requirements under 45 CFR part 74.32 or 74.34 or part 92.31 or 92.32, as applicable. |
| Trainee Costs | Allowable only under predoctoral and postdoctoral training grants. (See Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs in IIB for detailed information.) |

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| Items | Explanation of Allowable Costs |
|---|---|
| Transportation of Property | Allowable for freight, express, cartage, postage, and other transportation services relating to goods either purchased, in process, or delivered, including instances when equipment or other property is moved from one grantee to another. In a change-of-grantee situation, the cost of transportation may be charged to the grant at either the original or the new organization, depending on the circumstances and the availability of funds in the appropriate active grant account (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements). |
| Travel | Allowable as a direct cost where such travel will provide direct benefit to the project. |
| Travel / *Employees* | Consistent with the organization's established travel policy, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile.<br><br>Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the United States and its possessions and territories and also travel between the United States and Canada and within Canada.<br><br>Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country.<br><br>In all cases, travel costs are limited to those allowed by formally established organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. For-profit grantees' allowable travel costs may not exceed those established by the FTR, issued by GSA, including the maximum per diem and subsistence rates prescribed in those regulations. This information is available at http://www.gsa.gov. If a recipient organization has no established travel policy, those regulations will be used to determine the amount that may be charged for travel costs.<br><br>Grantees are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets if travel schedules can be planned in advance (such as for national meetings and other scheduled events).<br><br>Grantees must comply with the requirement Fly America Act (49 U.S.C. 40118) which generally provides that foreign air travel funded by Federal funds may only be conducted on U.S flag air carriers. For additional information regarding the Fly America Act and its exceptions, see Public Policy Requirements and Objectives—Fly America Act.<br><br>Applicants and grantees should consult application instructions to determine how to budget for travel costs under specific mechanisms and for certain types of travelers, because they are not all required to be budgeted as travel (e.g., research subjects). |
| Travel / *Research Patients* | If research patient care is an approved activity of the grant-supported project, the costs of transporting individuals participating in the research protocol to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose also may be allowable. (See also Research Patient Care in this exhibit.) |

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| Items | Explanation of Allowable Costs |
|---|---|
| Visa Costs | Allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual. It is the responsibility of the institution to monitor the status of the individual's visa and ensure they have sufficient time to fulfill the obligations of the research they are being paid for on the grant. However, if the person is already an employee and the cost in question is a visa renewal then this isn't a recruiting cost so the cost would not be an allowable charge to a grant. Expedited processing fees are generally unallowable unless and until they become part of standard processing fees. Fraud fees are allowable if they are required fees. Department of Homeland Security SEVIS Form I-901 is a required fee and is allowable. See also Recruitment Costs in this exhibit. |

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# 8 ADMINISTRATIVE REQUIREMENTS

## 8.1 CHANGES IN PROJECT AND BUDGET

In general, NIH grantees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the grantee's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a grantee makes certain budget modifications or undertakes particular activities. The grantee-initiated changes that may be made under the grantee's authority and the changes that require NIH approval are outlined below and, with respect to particular types of awards, activities, or recipients, in Subpart IIB. In addition, individual awards may restrict grantees' authorities to make budget and project changes without NIH prior approval. If NIH approval is required, it must be requested of, and obtained in writing from, the awarding IC GMO in advance of the change or obligation of funds as specified later in this chapter under Requests for Prior Approval.

Changes in project or budget resulting from NIH-initiated actions are discussed in other sections of this chapter.

### 8.1.1 NIH Standard Terms of Award

Federal administrative requirements allow agencies to waive certain cost-related and administrative prior approvals; these are known as expanded authorities. In 2001, NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances. Certain award instruments, grant programs, and types of recipients are routinely excluded from the authority to automatically carry over unobligated balances. This includes centers (P50, P60, P30, and others); cooperative agreements (U); Kirschstein-NRSA institutional research training grants (T); non-Fast Track Phase 1 SBIR and STTR awards (R43 and R41); clinical trials (regardless of activity code); and awards to individuals.

One or more of these authorities may be overridden by a special term or condition of the award. Grantees must review the NoA to determine if a particular authority is withheld for a specific grant.

Grantees must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. NIH may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

Several authorities have specific deadlines for submission of reports or for timely notification to the NIH awarding IC. Grantees should be aware that any consistent pattern of failure to adhere to those deadlines for reporting or notification will be grounds for excluding that grantee from a specific authority.

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**Exhibit 6. Summary of NIH Standard Terms of Award**

| Grantee Authorities as NIH Standard Terms of Award | Exceptions |
|---|---|
| Carryover of unobligated balances from one budget period to any subsequent period | Centers (P50, P60, P30 and others), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NoA indicates otherwise. |
| Cost-related prior approval changes, including research patient care costs and equipment | The cost would result in a change of scope. |
| Extension of final budget period of a project period without additional NIH funds (no-cost extension) | The grantee has already exercised its one-time authority to extend the award for up to 12 months. |
| Transfer of performance of substantive programmatic work to a third party (by consortium agreement) | The transfer would be to a foreign component or it would result in a change in scope. |

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### 8.1.1.1 Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period

Grantees should be aware that there is a difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the recipient and are considered to be obligations and, therefore, should not be reported as unobligated balances.

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the grantee has automatic carryover authority, or if prior approval is required by the NIH awarding IC. Note the authority to automatically carry over unobligated balances includes the authority to carryover from one competitive segment to another.

Automatic carryover of unobligated balances applies to all awards except centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials (regardless of activity code), and awards to individuals. For these grants, carryover of unobligated balances requires NIH awarding IC prior approval unless otherwise noted in the NoA. Other awards may be excluded from this authority through a special term or condition in the NoA.

For awards under SNAP (see Administrative Requirements—Monitoring—Reporting—Streamlined Non-Competing Award Process for applicability), funds are automatically carried over to the subsequent budget period. However, the grantee will be required to indicate, as part of the grant's progress report, whether any estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. The total approved budget amount includes current year and any carryover from prior years of the project period. If the unobligated balance is greater than 25 percent of the total approved budget, the grantee must provide an explanation and indicate plans for expenditure of those funds within the current budget year.

For awards that require an annual FFR, the amount to be automatically carried over must be specified under item 12, "Remarks."

For both SNAP and non-SNAP, when a grantee reports a balance of unobligated funds in excess of 25 percent of the total amount awarded for the budget period, the GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the grantee, including a revised budget, as part of the review.

If the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may restrict the grantee's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset NIH funding for a subsequent budget period, or use a combination of these actions. The GMO also may indicate whether the balance may be carried forward to a budget period other than the succeeding one. The GMO's decision about the disposition of the reported unobligated balance will be reflected in the terms and conditions of the NoA.

All Federal agencies are required by PL 101-510 to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, grantees must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision limits the availability of funds for carryover.

#### 8.1.1.2 Cost-Related Prior Approvals

NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope.

#### 8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds

The grantee may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original expiration date shown in the NoA if

- no term of award specifically prohibits the extension,
- no additional funds are required to be obligated by the NIH awarding IC, and
- the project's originally approved scope will not change.

Such an action affirms that additional work remains to be completed on the project and that resources are available to continue to support the project, or that additional time is needed to provide for an orderly closeout. The fact that funds remain at the expiration of the grant is not, in itself, sufficient justification for an extension without additional funds.

Grantees are encouraged to use the eRA Commons No-Cost Extension feature to electronically notify NIH that they are exercising their ***one-time*** authority to extend without funds the expiration date of an award. This extension may be up to 12 months beyond the final budget period end date. In the eRA Commons, this notification can be made up to the last day of the current project end date. An e-mail notification is automatically sent to the GMO and no further action is required.

Notifications submitted via e-mail or fax must be received by the GMO at the NIH awarding IC at least 10 days prior to the project period end date. Upon receipt of the notification, the GMO will process and acknowledge the extension. If the no-cost extension notification is submitted late, the extension

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notification automatically becomes a request and requires the approval of the IC Chief GMO. (See Administrative Requirements—Prior Approval Requirements for extension requiring additional funds.)

In extending the final budget period of the project period through this process, the grantee agrees to update all required certifications and assurances, including but not limited to those pertaining to human subjects and animal welfare, in accordance with applicable regulations and policies. Grantees are reminded that all terms and conditions of the award apply during the extension period.

Grantees may not extend project periods that were previously extended by the NIH awarding IC. Any additional project period extension requires NIH prior approval. (See Administrative Requirements—Prior Approval Requirements for extensions requiring additional funds.)

#### 8.1.1.4 Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement

Prior approval by the NIH awarding IC is not required to transfer the performance of already peer reviewed programmatic work unless the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

### 8.1.2 Prior Approval Requirements

This section describes the activities and/or expenditures that require NIH prior approval. NIH prior approval requirements are summarized in Exhibit 7, which is provided for guidance only. For the prior approval requirements specified in the exhibit, approval is required whether or not the change has a budgetary impact. The circumstances under which prior approval is required also are summarized in the exhibit.

Grantees also should consult Subpart IIB for prior approval requirements that apply to specific mechanisms, types of grants, and types of recipients.

Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to the GMO.

**Exhibit 7. Summary of Actions Requiring NIH Prior Approval**

| NIH prior approval is required for | Under the following circumstances |
|---|---|
| Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension (8.1.2.1) | All instances. |
| A&R (8.1.2.2) | Rebudgeting into A&R costs that would exceed 25 percent of the total approved budget for a budget period.<br><br>If rebudgeting would not meet this threshold but would result in a change in scope.<br><br>Any single A&R project exceeding $500,000. |

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| NIH prior approval is required for | Under the following circumstances |
|---|---|
| Capital expenditures (construction, land, or building acquisition) (8.1.2.3) | All instances. Also, any proposals to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds. |
| Carryover of unobligated balances (8.1.2.4) | If the NoA indicates that the grantee does not have the authority to automatically carry over unobligated balances. |
| Change in scope (8.1.2.5) | All instances. |
| Change in status of the PD/PI or senior/key personnel named in the NoA (8.1.2.6) | Withdrawal from the project; absence for any continuous period of 3 months or more; reduction of the level of effort devoted to project by 25 percent or more from what was approved in the initial competing year award. |
| Change of grantee organization (8.1.2.7) | All instances. |
| Change of grantee organization status (8.1.2.8) | All instances. |
| Deviation from award terms and conditions (8.1.2.9) | All instances. Includes undertaking any activities disapproved or restricted as a condition of the award. |
| Foreign component added to a grant to a domestic organization (8.1.2.10) | All instances. |
| Need for additional NIH funding (8.1.2.11 and 8.1.2.12) | All instances, including extension of a final budget period of a project period with additional funds. |
| Pre-award costs (8.1.2.13) | More than 90 days before effective date of the initial budget period of a new or competing continuation award; always at the grantee's own risk. |
| Rebudgeting funds from trainee costs (8.1.2.14) | All instances. |
| Rebudgeting of funds between construction and non-construction work (8.1.2.15) | All instances. |
| Retention of research grant funds when CDA awarded (8.1.2.16) | All instances. |

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### 8.1.2.1 Additional No-cost Extension or Extension Greater Than 12 Months or Late Notification of Initial No-Cost Extension

The NIH Standard Terms of Award provide the grantee the authority to extend the final budget period of a previously approved project period one time for a period of up to 12 months beyond the original expiration date down in the NoA. Any additional project period extension beyond the initial extension of up to 12 months requires NIH prior approval. The request should include a description of the project activities that require support during the extension and a statement about the funds available to support the extension. Further any late notification of the initial no-cost extension provided by the NIH Standard Terms of Award also requires prior approval.

#### 8.1.2.2 Alterations and Renovations

NIH prior approval is required if a grantee wishes to rebudget more than 25 percent of the total approved budget for a budget period into A&R costs. NIH prior approval also is required for lesser rebudgeting into A &R costs if the rebudgeting would result in a change in scope. If rebudgeting results in an A&R project exceeding $500,000, NIH always will consider the rebudgeting to be a change in scope. (See the Construction Grants chapter in IIB for documentation requirements for A&R projects exceeding $500,000).

#### 8.1.2.3 Capital Expenditures

Capital expenditures for land or buildings require NIH prior approval. In addition, real property acquired with NIH grant funds may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the grantee without the written prior approval of the NIH awarding IC or its successor organization.

#### 8.1.2.4 Carryover of Unobligated Balances

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the grantee has automatic carryover authority or if prior approval is required by the NIH awarding IC. When NIH prior approval is required, the AOR should submit a request to the GMO that includes at a minimum the following information:

- A detailed budget by direct cost category with the F&A cost information (base and rate) for the proposed use of the carryover funds. If personnel costs are requested, include a detailed breakdown of personnel costs, including base salary, salary requested and effort to be spent on the project during the extension.
- A scientific justification for the use of funds.
- The reason for the unobligated balance.

#### 8.1.2.5 Change in Scope

In general, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the grantee must obtain prior approval from the NIH awarding IC for a change in scope. A change in scope is a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project. The grantee must make the initial determination of the significance of a change and should consult with the GMO as necessary.

Potential indicators of a change in scope include, but are not limited to, the following:

- Change in the specific aims approved at the time of award.
- Substitution of one animal model for another.
- Change from the approved use of live vertebrate animals or involvement of human subjects.
- Shift of the research emphasis from one disease area to another.
- A clinical hold by FDA under a study involving an IND or an IDE.

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- Application of a new technology, e.g., changing assays from those approved to a different type of assay.

- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. If the third party is a foreign component, NIH prior approval is always required.

- Change in other senior/key personnel not specifically named in the NoA (see Change in Status, Including Absence, of PD/PI and Other Senior/Key Personnel Named in the NoA below for requirements for NIH approval of alternate arrangements for or replacement of named senior/key personnel).

- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded. For example, if the award budget for total costs is $200,000, any rebudgeting that would result in an increase or decrease of more than $50,000 in a budget category is considered significant rebudgeting. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements. Significant rebudgeting does not apply to modular grants.

- Incurrence of research patient care costs if costs in that category were not previously approved by NIH or if a grantee desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category.

- Purchase of a unit of equipment exceeding $25,000.

#### 8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA

The grantee is required to submit a prior approval request to the GMO if the PD/PI or other senior/key personnel specifically named in the NoA will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of initial competing year award (for example, a proposed change from 40 percent effort to 30 percent or less effort or in calendar months a change from 4.8 to 3.6 calendar months). Once approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved, adjusted level. NIH must approve any alternate arrangement proposed by the grantee, including any replacement of the PD/PI or senior/key personnel named in the NoA.

The request for approval of a substitute PD/PI or senior/key person should include a justification for the change, the biographical sketch of the individual proposed, other sources of support, and any budget changes resulting from the proposed change. If the arrangements proposed by the grantee, including the qualifications of any proposed replacement, are not acceptable to the NIH awarding IC, the grant may be suspended or terminated. If the grantee wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the GMO, in writing, of its wish to terminate, and NIH will forward closeout instructions.

The requirement to obtain NIH prior approval for a change in status pertains only to those personnel NIH designates in the NoA regardless of whether the applicant organization designates others as senior/key personnel for its own purposes.

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### 8.1.2.7 Change of Grantee Organization

NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the expiration of the approved project period (competitive segment). A change of grantee organization may be accomplished under most NIH grants, including construction grants, if any of the following conditions are met:

- The original grantee has agreed to relinquish responsibility for an active project before the expiration of the approved project period. This includes any proposed change of grantee as a result of a PD/PI on a research project transferring from one organization to another organization. The project under the same PD/PI may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable F&A costs) for the remaining period.

- The grant to be transferred has been terminated in accordance with 45 CFR part 74.61 or 92.43.

- A non-competing continuation award that is within an approved project period has been withheld because of the grantee's actions (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support).

A change of grantee that involves the transfer of a grant to or between foreign institutions or international organizations also must be approved by the IC's Advisory Council or Board.

A grant to an individual may not be transferred.

A successor-in-interest or a name change is not considered a change of grantee (see Change in Grantee Organizational Status below).

A change of grantee organization may involve the transfer of equipment purchased with grant funds. The transfer may be accomplished as part of the original grantee's relinquishment of the grant; otherwise, NIH reserves the right to transfer title to equipment to the new organization as indicated in Administrative Requirements—Management Systems and Procedures—Property Management System Standards.

A change of grantee request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any proposed changes in the scope of the project. A change may be made without peer review, provided the PD/PI plans no significant change in research objectives and the facilities and resources at the new organization will allow for successful performance of the project. If these conditions or other programmatic or administrative requirements are not met, the NIH awarding IC may require peer review or may disapprove the request and, if appropriate, terminate the award.

A change of grantee organization request must be made before the anticipated start date at the new organization and preferably several months in advance. Failure to provide timely notification may result in disapproval of the request or significant delays in processing.

A request for a change of grantee organization must be submitted to the GMO and the original institution must include an Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant (PHS 3734) (relinquishing statement). A final FFR and Final Invention Statement are due

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to NIH from the relinquishing organization no later than 90 days after the end of NIH support of the project.

The proposed new grantee must provide the GMO with a change of institution application. Until such time as NIH develops the capability to allow electronic submission of these applications, the applicants should use the PHS 398 application form pages. If the original award was the result of a modular application, modular procedures apply to the request for change of grantee. The application from the proposed grantee should include, at a minimum, the following:

- Face page.
- Budget pages (current and future years). (Under awards resulting from modular applications, the application should include narrative budget information, including total direct and F&A costs for the current budget period and, if future budget periods remain, information about the number of modules and the basis for computing F&A costs for all future years.)
- Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel.
- If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- Updated "other support" page(s), if necessary.
- Resources page, including probable effect of the move on the project.
- Checklist page.
- Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
- Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment).

NIH may request additional information necessary to accomplish its review of the request. Acceptance of a relinquishing statement by NIH does not guarantee approval of a transfer application for the continued funding of a project.

NIH will accomplish a change of grantee organization by issuing a revised NoA to the original grantee reflecting the revised budget/project period end dates, deletion of any future-year support, and deobligation of remaining funds, if applicable. (A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement.) Concurrently, the new grantee will receive the NoA reflecting the direct cost balance reported on the relinquishing statement plus applicable F&A costs, if funds are available. If the change of grantee organization occurs on the anniversary date of the project, the NoA to the new grantee will reflect the previously committed direct cost level plus applicable F&A costs if funds are available. This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward.

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### 8.1.2.8 Change in Grantee Organizational Status

Grantees must give NIH advance notice of the following types of change in organizational status (not a change of grantee organization as described above):

- ***Merger.*** Legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change normally will apply.

- ***Successor-in-Interest (SII).*** Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the grantee or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.

- ***Name Change.*** Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a grantee.

Advance notification is required to ensure that the grantee remains able to meet its legal and administrative obligations to NIH, and payments are not interrupted.

Grantees are encouraged to contact the GMO of the lead NIH awarding IC to explain the nature of the change in organizational status and receive guidance on whether it will be treated as a name change or SII. The lead awarding IC ordinarily will be the IC with which the organization has the most NIH grants. NIH reserves the right to review the material provided, seek clarification or additional information, and make an independent determination.

A grantee's formal request for a change in organizational status should be submitted to NIH as soon as possible so that NIH can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For a SII, a letter signed by the AORs of the current grantee (transferor) and the successor-in-interest (transferee) must be sent to the lead NIH awarding IC, following consultation with the GMO of that awarding IC. The letter must include the following:

- Stipulate that the transfer will be properly affected in accordance with applicable law.

- Indicate that the transferor relinquishes all rights and interests in all of the affected grants.

- Request that the awarding IC(s) modify its (their) records to reflect the transferee as the grantee of record.

- State the effective date of the transfer.

- Provide the transferee's EIN. If EIN is new, include completed Form W-9.

- Include verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance).

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- Include a list of all affected NIH grants (active and pending) with the following information for each:
    - Complete grant number (e.g., 5 R01 GM 12345-04).
    - Name(s) of PD/PI(s).
    - Current budget period and project period.
    - The total direct costs (as originally recommended) plus applicable F&A costs for each remaining budget period. If the SII will occur during a budget period rather than on the anniversary date, the transferor also must provide estimated levels of current-year direct and F&A costs remaining as of the SII effective date. The estimate may be reported on the PHS 3734 (Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant) or an equivalent relinquishing statement for each affected grant or may be itemized by grant number as an attachment to the letter.
- Include a complete face page (PHS 398) for each affected grant showing the transferee as the applicant organization. Each face page must be signed by an AOR at the transferee organization.
- Include a copy of the current negotiated F&A rate agreement for the transferee.

In order to be recognized as the SII, the "new" (transferee) organization must meet each grant program's eligibility requirements; except for grants awarded under the SBIR/STTR programs. See Small Business Innovation Research and Small Business Technology Transfer Programs—Eligibility in IIB for additional guidance. Upon review and acceptance of this information, NIH will revise the NoA(s) to show the transferee as the grantee of record.

For name changes, the grantee's written notification to the lead NIH awarding IC must include the effective date of the change. Revised face pages are not required for name changes because name changes are reported and processed with the next award action (e.g., non-competing continuation award).

#### 8.1.2.9 Deviation from Award Terms and Conditions, including Restrictions in the NoA

NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NoA, including those in the NIHGPS. This includes undertaking any activities disapproved or restricted as a condition of the award.

#### 8.1.2.10 Foreign Component Added to a Grant to a Domestic Organization

Adding a foreign component under a grant to a domestic organization requires NIH prior approval.

#### 8.1.2.11 Need for Additional NIH Funding without Extension of Budget and Project Period

A request for additional funding for a current budget period to meet increased costs that are within the scope of the approved application, but that were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted, is a non-competing supplemental application. Such requests are submitted, in writing, directly to the GMO and are not required to compete with other applications for funding. Other grantee-initiated requests for supplemental funding during a current budget period are considered to change the scope of the approved project and may be required to compete for funding with other applications.

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#### 8.1.2.12 Need for Additional NIH Funding with Extension of the Final Budget Period of a Project Period

A request for a non-competing extension of the final budget period of a project period with a minimal amount of additional funds should be submitted to the GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests usually are for a period of up to 12 months, based on a need that additional work remains to be completed on the project and that resources are available to continue to support the project, or to permit orderly phase-out of project activities for which there will be no further NIH support. The request must specify the proposed revised ending date and must include justification for both the extension and the additional funds requested. Special justification will be required for an extension that would exceed 12 months. NIH will not approve such requests if the primary purpose of the proposed extension is to permit the use of unobligated balances of funds. All terms and conditions of the award apply during the extended period.

#### 8.1.2.13 Pre-Award Costs

See Cost Considerations—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs.

#### 8.1.2.14 Rebudgeting of Funds from Trainee Costs

The rebudgeting of amounts previously awarded for trainee costs (stipends, tuition, and fees) to other categories of expense requires NIH prior approval. This excludes trainee travel, which NIH does not consider to be a trainee cost, and training-related expenses (see Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Rebudgeting of Funds in IIB).

#### 8.1.2.15 Rebudgeting of Funds Between Construction and Non-construction Work

Under awards that provide for both construction and non-construction work, NIH prior approval is required to transfer funds between the two types of work.

#### 8.1.2.16 Retention of Research Grant Funds When a Career Development Award is Issued

Funds budgeted under an NIH grant for an individual's salary and fringe benefits, but available as a result of receiving a K award for that individual, may not be used for any other purpose without NIH prior approval.

### 8.1.3 Requests for Prior Approval

All requests for NIH awarding IC prior approval must be made in writing (including submission by e-mail) to the GMO no later than 30 days before the proposed change, and signed by the AOR. If the request is e-mailed, it must provide evidence of the AOR's approval; a cc to the AOR is not acceptable. Failure to obtain required prior approval from the appropriate awarding IC may result in the disallowance of costs, termination of the award, or other enforcement action within NIH's authority.

E-mail requests must be clearly identified as prior approval requests, must reflect the complete grant number in the subject line, and should be sent by the AOR to the GMO that signed the NoA. Contact information is provided on each NoA and is also available in the eRA Commons. E-mail addresses for NIH staff can be also obtained from the NIH Enterprise Directory at: https://ned.nih.gov/search/. E-mail requests must include the name of the grantee, the name of the initiating PD/PI, the PD/PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOR.

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The GMO will review the request and provide a response to the AOR indicating the final disposition of the request, with copies to the PD/PI and to the cognizant NIH PO. Only responses provided by the GMO are considered valid. Grantees that proceed on the basis of actions by unauthorized officials do so at their own risk, and NIH is not bound by such responses.

Whenever grantees contemplate rebudgeting or other post-award changes and are uncertain about the need for prior approval, they are strongly encouraged to consult, in advance, with the GMO.

Under a consortium agreement or contract, the prior approval authority usually is the prime grantee. However, the prime grantee may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the NIH grant. If an action by a consortium participant will result in a change in the overall grant project or budget requiring NIH approval, the prime grantee must obtain that approval from NIH before giving its approval to the consortium participant.

## 8.2 AVAILABILITY OF RESEARCH RESULTS: PUBLICATIONS, INTELLECTUAL PROPERTY RIGHTS, AND SHARING RESEARCH RESOURCES

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It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also Availability and Confidentiality of Information—Confidentiality of Information—Access to Research Data in Part I for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR part 401, apply.

As long as grantees abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the grantee to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources—"research tools"—may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

### 8.2.1 Rights in Data (Publication and Copyrighting)

In general, grantees own the rights in data resulting from a grant-supported project. Special terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable RFA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. For this purpose, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films,

sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.

Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages grantees to arrange for publication of NIH-supported original research in primary scientific journals. Grantees also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the grantee from making copies for its own use (as provided in 45 CFR parts 74.36 and 92.34). The disposition of royalties and other income earned from a copyrighted work is addressed in Administrative Requirements—Management Systems and Procedures—Program Income.

For each publication that results from NIH grant-supported research, grantees must include an acknowledgment of NIH grant support and a disclaimer stating the following:

> "This publication was made possible by Grant Number _____ from _____" or "The project described was supported by Grant Number _____ from _____" and "Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the [name of awarding office or NIH]."

If the grantee plans to issue a press release concerning the outcome of NIH grant-supported research, it should notify the NIH awarding IC in advance to allow for coordination. See also Appropriation Mandates—Acknowledgment of Federal Funding for additional guidance when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money.

Publications resulting from work performed under an NIH grant-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports and Administrative Requirements—Closeout—Final Reports—Final Progress Report). When publications are available electronically, the url or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report. See also NIH Public Access Policy below for additional requirements for publications resulting from NIH funded research.

## 8.2.2 NIH Public Access Policy

The NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH funded research at the NIH NLM PMC, a free digital archive of full-text biomedical and life sciences journal literature (http://www.pubmedcentral.nih.gov/). Under the policy NIH-funded investigators are required by Federal law to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The author's final peer-reviewed manuscript is defined as the

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final version accepted for journal publication on or after 4/7/2008, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this policy. Applicants citing articles in NIH applications, proposals, and progress reports that fall under the policy, were authored or co-authored by the applicant and arose from NIH support must include the PMCID or NIHMS ID. The NIHMSID may be used to indicate compliance with the Public Access Policy in applications and progress reports for up to three months after a paper is published. After that period, a PMCID must be provided to demonstrate compliance.

This policy applies to all peer-reviewed articles resulting from research supported in whole or in part with direct costs from NIH, including research grant and career development awards, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, SBIR/STTR awards, and NIH intramural research studies.

Additional information can be found at: http://publicaccess.nih.gov/.

## 8.2.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act. See the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page: http://inventions.nih.gov.

Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

To provide further clarification of the NIH policy on disseminating unique research resources, NIH published *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999; http://grants.nih.gov/grants/intell-property_64FR72090.pdf). This document will assist grantees in determining reasonable terms and conditions for disseminating and acquiring research tools.

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding IC, the grantee also must provide a copy of documents or a sample of any material developed under an NIH grant award. The grantee may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see Administrative Requirements—Management Systems and Procedures—Program Income).

To facilitate the availability of unique or novel materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if

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appropriate, to entities such as the American Type Culture Collection or other repositories and should ensure that those entities distribute them in a way that is consistent with the above referenced *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

### 8.2.3.1 Data Sharing Policy

NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. All investigator-initiated applications with direct costs of $500,000 or more (excluding consortium F&A costs) in any single year are expected to address data-sharing in their application. In some cases, FOAs may request data-sharing plans for applications that are less than $500,000 (excluding consortium F&A costs) in any single year.

NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the HIPAA Privacy Rule (see Public Policy Requirements and Objectives—Confidentiality of Patient Records: Health Insurance Portability and Accountability). The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to meet these expectations should promptly contact the GMO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of an award.

### 8.2.3.2 Sharing Model Organisms

All applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

This expectation is for **all** applications where the development of model organisms is anticipated, regardless of funding amount.

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For additional information on this policy, see the NIH Model Organism for Biomedical Research Web site at: http://www.nih.gov/science/models/.

#### 8.2.3.3 Policy for Genome-Wide Association Studies (GWAS)

NIH is interested in advancing GWAS to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition.

All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. For additional information see: http://grants.nih.gov/grants/gwas/.

### 8.2.4 Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212) and the related EO 12591 (April 10, 1987) provide incentives for the practical application of research supported through Federal funding agreements. To be able to retain rights and title to inventions made with Federal funds, so-called "subject" inventions, the grantee must comply with a series of regulations that ensure the timely transfer of the technology to the private sector, while protecting limited rights of the Federal government.

The regulations apply to any subject invention—defined as any invention either conceived or first actually reduced to practice in the performance of work under the Federal award—and to all types of recipients of Federal funding. This includes non-profit entities and small businesses or large businesses receiving funding through grants, cooperative agreements, or contracts as direct recipients of funds, or as consortium participants or subcontractors under those awards.

Some of the steps required by the regulation to retain intellectual property rights to subject inventions include:

- Report all subject inventions to NIH.
- Make efforts to commercialize the subject invention through patent or licensing.
- Formally acknowledge the Federal government's support in all patents that arise from the subject invention.
- Formally grant the Federal government a limited use license to the subject invention.

Exhibit 8 summarizes recipient responsibilities for invention reporting as specified in the regulations in 37 CFR part 401. Grantees should refer to 37 CFR part 401 (available on the Interagency Edison site: https://s-edison.info.nih.gov/iEdison/) for a complete discussion of the regulations.

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**Exhibit 8. Extramural Invention Reporting Compliance Responsibilities**

| Invention Reporting Requirement | Action Required | When Action Must Be Taken | Discussion | 37 CFR part 401 Reference |
|---|---|---|---|---|
| **Employee Agreement to Disclose All Inventions** | Grantee employees working under the funding award (e.g., PD/PI) must sign an agreement to abide by the terms of the Bayh-Dole Act and the NIHGPS as they relate to intellectual property rights. | At time of employment-term of employment. | Grantee organizations and consortium participants must have policies in place regarding ownership of intellectual property, including conflict of interest issues. | 401.14(f)(2) |
| **Invention Report and "Disclosure"** | The grantee organization must submit to NIH a report of any subject invention. This includes a written description (the so-called "invention disclosure") of the invention that is complete in technical detail. | Within 2 months of the inventor's initial report of the invention to the grantee organization. | There is no single format for disclosing the invention to the Federal government. The report must identify inventor(s), NIH grant number, and date of any public disclosure. | 401.14(a)(2)<br>401.14(c)(1) |
| **Rights to Consortium Participant Inventions** | Consortium participants under NIH grants retain rights to any subject inventions they make. | Within 2 months of the inventor's initial report of the invention to the consortium participant. (The consortium participant has the same invention reporting obligations as the grantee.) | The grantee cannot require ownership of a consortium participant's subject inventions as a term of the consortium agreement. | 401.14(g)(1)<br>401.14(g)(2) |
| **Election of Title to Invention** | The grantee must notify NIH of its decision to retain or waive title to invention and patent rights. | Within 2 years of the initial reporting of the invention to NIH. | | 401.14(b)<br>401.14(c)(2)<br>401.14(f)(1) |

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| Invention Reporting Requirement | Action Required | When Action Must Be Taken | Discussion | 37 CFR part 401 Reference |
|---|---|---|---|---|
| **Confirmatory License** | For each invention, the grantee must provide a user license to NIH for each invention. | When the initial non-provisional patent application is filed. | | 401.14(f)(1) |
| **Patent Application** | The grantee must inform NIH of the filing of any non-provisional patent application. The patent application must include a Federal government support clause. | Within 1 year after election of title, unless there is an extension. | Initial patent application is defined as a non-provisional U.S. application. The patent application number and filing date must be provided. The following language is to be used on patent application: "This invention was made with government support under (identify the funding award) awarded by (identify the IC and Federal Agency). The government has certain rights in the invention. All communications for such requests must be sent to OER." | 401.14(c)(3)<br>401.2(n)<br><br>401.14(f)(4) |
| **Assignment of Rights to Third Party** | If the grantee is a non-profit organization, it must ask NIH approval to assign invention or U.S. patent rights to any third party, including the inventor(s). | As needed. All communication for such requests must be sent to OER. The NIH Office of Technology Transfer serves in an advisory capacity to OER for the processing of such assignment requests. | Grantees that are for-profit entities (including small businesses) do not need to ask approval, but ongoing reporting remains a requirement for each invention. | 401.14(k) |
| **Issued Patent** | The grantee must notify NIH that a patent has been issued. | When the patent is issued. | The patent issue date, number, and evidence of Federal government support clause must be provided. | 401.5(f)(2) |

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| Invention Reporting Requirement | Action Required | When Action Must Be Taken | Discussion | 37 CFR part 401 Reference |
|---|---|---|---|---|
| **Extension of Time to Elect Title or File Patent** | The grantee may request an extension of up to 2 years for election of title, or an extension of up to 1 year for filing a patent application. | As needed. | Request for extension of time must be made. Such requests are preapproved. | 401.14(c)(4) |
| **Change in Patent Application Status** | The grantee must notify NIH of changes in patent status. | At least 30 days before any pending patent office deadline. | This notification allows NIH to consider continuing the patent action. | 401.14(f)(3) |
| **Invention Utilization Report** | The grantee must submit information about the status of commercialization of any invention for which title has been elected. | Annually. | This report gives an indication of whether the objectives of the law are being met. Specific reporting requirements can be found in iEdison (http://iEdison.gov). | 401.14(h) |
| **Annual Invention Statement** | The grantee must indicate any inventions made during the previous budget period on all grant awards. | Part of all competing applications and non-competing continuation progress reports. | The information is requested as a checklist item on the PHS 398 application and on the non-competing continuation progress report. | PHS 398 and PHS 2590 |
| **Final Invention Statement and Certification** | The grantee must submit to the NIH awarding IC GMO a summary of all inventions made during the entire term of each grant award. | Within 90 days after the project period (competitive segment) ends. | Required information is specified on the HHS 568 form. If no inventions occurred during the project period, a negative report must be submitted. | 401.14(f)(5) |

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Failure of the grantee to comply with any of these or other regulations cited in 37 CFR part 401 may result in the loss of patent rights or a withholding of additional grant funds.

The Bayh-Dole Act includes provisions for the grantee to assign invention rights to third parties. Grantees that are non-profit organizations must request NIH approval for the assignment. If the assignment is approved and the rights are assigned to a third party, invention and patent reporting requirements apply to the third party. The grantee should review existing agreements with third parties and revise them, as appropriate, to ensure they are consistent with the terms and conditions of their NIH grant awards and that the objectives of the Bayh-Dole Act are adequately represented in the assignment.

Any invention made using funds awarded for educational purposes, e.g. fellowships, training grants or certain types of career development awards, is not considered a subject invention and therefore is not subject to invention reporting requirements (as provided in 45 CFR part 74 and 37 CFR part 401.1(b)). The grantee should seek the advice of NIH to verify whether any invention made under a career development award should be considered a subject invention.

Details regarding invention reporting and iEdison are discussed under Administrative Requirements—Monitoring—Reporting—Invention Reporting.

All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to the Division of Extramural Inventions and Technology Resources Branch, OPERA, OER. See Part III for contact information.

## 8.3 MANAGEMENT SYSTEMS AND PROCEDURES

Grantee organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Grantees may use their existing systems to manage NIH grant funds and activities as long as they are consistently applied regardless of the source of funds and meet the standards and requirements set forth in 45 CFR part 74 or part 92 and the NIHGPS. NIH may review the adequacy of those systems and may take appropriate action, as necessary, to protect the Federal government's interests, including, but not limited to, the use of special terms and conditions. NIH also will oversee the grantee's systems as part of its routine post-award monitoring. The grantee's systems also are subject to audit (see Administrative Requirements—Monitoring—Audit).

NIH seeks to foster within grantee organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

### 8.3.1 Financial Management System Standards

Grantees are required to meet the standards and requirements for financial management systems set forth or referenced in 45 CFR part 74.21 or 92.20, as applicable. The standards and requirements for a financial management system are essential to the grant relationship. NIH cannot support the research unless it has assurance that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded.

Grantees must have in place accounting and internal control systems that provide for appropriate monitoring of grant accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify large unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds. Grantees must notify NIH when problems are identified.

A grantee's failure to establish adequate control systems constitutes a material violation of the terms of the award. Under these circumstances, NIH may include special conditions on awards or take any of the range of actions specified in Administrative Requirements—Enforcement Actions, as necessary and appropriate.

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## 8.3.2 Program Income

Program income is gross income—earned by a grantee, a consortium participant, or a contractor under a grant—that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed; charges for the use or rental of real property, equipment or supplies acquired under the grant; the sale of commodities or items fabricated under an award; charges for research resources; registration fees for grant-supported conferences, and license fees and royalties on patents and copyrights. (Note: Program income from license fees and royalties from copyrighted material, patents, and inventions is exempt from reporting requirements unless otherwise specified in the terms and conditions of award.) The requirements for accountability for these various types of income under NIH grants are specified in this subsection. Accountability refers to whether NIH will specify how the income is to be used and whether the income needs to be reported to NIH and for what length of time. Unless otherwise specified in the terms and conditions of the award, NIH grantees are not accountable for program income accrued after the period of grant support.

NIH applies the additive alternative to all grantees, including for-profit entities, unless there is a concern with the recipient or activity and NIH uses special terms and conditions, or the program requires a different program income alternative. NIH may require a different use of program income if a grantee has deficient systems; if the PD/PI has a history of frequent, large annual unobligated balances on previous grants; or if the PD/PI has requested multiple extensions of the final budget period of the project period. Regardless of the alternative applied, program income may be used only for allowable costs in accordance with the applicable cost principles and the terms and conditions of the award. Each NoA will indicate the allowable treatment of program income. Program income alternatives and their usage are noted below in Exhibit 9.

Consortium agreements and contracts under grants are subject to the terms of the agreement or contract with regard to the income generated by the activities, but the terms specified by the grantee must be consistent with the requirements of the grant award. Program income must be reported by the grantee as discussed in this subsection.

### 8.3.2.1 Reporting Program Income

The amount of program income earned and the amount expended must be reported on the appropriate annual financial report, currently the FFR. Any costs associated with the generation of the gross amount of program income that are not charged to the grant should be deducted from the gross program income earned, and the net program income should be the amount reported. Program income must be reported in the Program Income section of the FFR (lines 10 L – O). (See Administrative Requirements—Monitoring—Reporting—Financial Reporting.) For awards under SNAP, the amount of program income earned must be reported in the non-competing continuation progress report.

Income resulting from royalties or licensing fees is generally exempt from reporting as program income.

When applicable, income earned from the sale of equipment must be reported on the FFR for the period in which the proceeds are received in accordance with the reporting requirements for the program income alternative specified. Amounts due NIH for unused supplies must be reflected as a credit to the grant on the FFR using line 10 m.

Reporting requirements for accountable income accrued after grant support ends will be specified in the NoA.

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**Exhibit 9. Use and Applicability of Program Income Alternatives**

| Program income alternative | Use of program income | Applicability |
|---|---|---|
| Additive Alternative | Added to funds committed to the project or program and used to further eligible project or program objectives. | Applies to all NIH awards unless there is a concern with the recipient or activity or the program requires a different alternative. |
| Deductive Alternative | Deducted from total allowable costs of the project or program to determine the net allowable costs on which the Federal share of costs will be based. | Available for use by NIH programs on an exception basis. |
| Combination Alternative | Uses all program income up to (and including) $25,000 as specified under the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative. | Available for use by NIH programs on an exception basis. |
| Matching Alternative | Used to satisfy all or part of the non-Federal share of a project or program. | Available for use by NIH programs that require matching. |

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### 8.3.2.2 Sale of Real Property, Equipment, and Supplies

The requirements that apply to the sale of real property are addressed in the Construction Grants chapter. For equipment and supplies purchased under NIH grants for basic or applied research by non-profit institutions of higher education or non-profit organizations whose principal purpose is the conduct of scientific research, the grantee is exempt from any requirement to account to NIH for proceeds from the sale of the equipment or supplies; however, NIH has certain rights with respect to such property as specified in Administrative Requirements—Management Systems and Procedures—Property Management System Standards.

All other types of grants and grantees are subject to the requirements in 45 CFR part 74.34 or 92.32 if title to the equipment vests in the grantee rather than in NIH. If the grant-supported project or program for which equipment was acquired is still receiving NIH funding at the time of sale, the grantee must credit the NIH share of the proceeds to the grant and use that amount under the deductive alternative for program income. If the grantee is no longer receiving NIH grant support, the amount due should be paid in accordance with instructions from NIH. These grants and grantees also are subject to the requirements in 45 CFR part 74.35 or 92.33 with respect to the use or sale of unused supplies. If the grantee retains the supplies for use on other than federally sponsored activities, an amount is due NIH as if they were sold.

### 8.3.2.3 Royalties and Licensing Fees from Copyrights, Inventions, and Patents

NIH grantees do not have to report program income resulting from royalties or licensing fees from sale of copyrighted material unless specific terms and conditions of the award provide otherwise. The NoA may include special terms and conditions if commercialization of an invention is an anticipated outcome of a research project.

However, the regulations implementing the Bayh-Dole Act (37 CFR part 401.14(h)) require reporting of income resulting from NIH-funded inventions and patents. Specifically, as part of the annual invention utilization report, grantees must report income generated by all subject inventions to which title has been

elected and by inventions such as research tools that have been licensed but not patented (see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources and Administrative Requirements—Monitoring—Reporting).

## 8.3.3 Property Management System Standards

Generally, grantees may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH grant funds, provided they observe the requirements in 45 CFR parts 74.30 through 74.37 or parts 92.31 through 92.34, as applicable, and the following. State governments will use, manage, and dispose of equipment acquired under a grant in accordance with state laws and procedures as specified in 45 CFR part 92.32.

The dollar threshold for determining the applicability of several of the requirements in those regulations is based on the unit acquisition cost of an item of equipment. As defined in 45 CFR part 74.2, the acquisition cost of an item of equipment to the grantee includes necessary modifications and attachments that make it usable for the purpose for which it was acquired or fabricated. When such accessories or attachments are acquired separately and serve to replace, enhance, supplement, or otherwise modify the equipment's capacity and they individually meet the definition of equipment (see Glossary in Part I), any required NIH prior approval for equipment must be observed for each item. However, the aggregate acquisition cost of an operating piece of equipment will be used to determine the applicable provisions of 45 CFR part 74.34 or 92.32. If property is fabricated from individual component parts, each component must itself be classified as equipment if it meets the definition of equipment. In this case, the aggregate acquisition cost of the resulting piece of equipment will determine the appropriate accountability requirements in 45 CFR part 74.34 or 92.32.

Grantees are required to be prudent in the acquisition of property under a grant-supported project. It is the grantee's responsibility to conduct a prior review of each proposed property acquisition to ensure that the property is needed and that the need cannot be met with property already in the possession of the organization. If prior approval is required for the acquisition, the grantee must ensure that appropriate approval is obtained in advance of the acquisition. The grantee also must follow appropriate procurement procedures in acquiring property as specified in Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements.

Recipients of NIH grants other than Federal institutions cannot be authorized to use Federal supply sources.

### 8.3.3.1 Real Property

See Construction Grants—Real Property Management Standards in IIB for requirements that apply to the acquisition, use, and disposition of real property. Fixed equipment that is part of a construction grant is subject to those requirements.

### 8.3.3.2 Equipment and Supplies

In general, title to equipment and supplies acquired by a grantee with NIH funds vests in the grantee upon acquisition, subject to the property management requirements of 45 CFR parts 74.31, 74.34, 74.35, and 74.37, or parts 92.32 and 92.33. Limited exceptions to these general rules are States, which may use, manage, and dispose of equipment acquired under a grant in accordance with State laws and procedures, and certain research grant recipients with exempt property. These requirements do not apply to equipment for which only depreciation or use allowances are charged, donated equipment, or equipment acquired primarily for sale or rental rather than for use.

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#### 8.3.3.2.1 Exempt Property

Under the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6306, NIH may permit non-profit institutions of higher education and non-profit organizations whose primary purpose is the conduct of scientific research to obtain title to equipment and supplies acquired under grants for support of basic or applied scientific research without further obligation to the Federal government. However, there is one exception: NIH has the right to require transfer of title to equipment with an acquisition cost of $5,000 or more to the Federal government or to an eligible third party named by the NIH awarding IC under the conditions specified in 45 CFR part 74.34(h). NIH may exercise this right within 120 days of the completion or termination of an award or within 120 days of receipt of an inventory, as provided in 45 CFR part 74.34(h)(2), whichever is later.

#### 8.3.3.2.2 Nonexempt Property

All other equipment and supplies acquired under all other NIH grant-supported projects by any other type of grantee are subject to the full range of acquisition, use, management, and disposition requirements of 45 CFR parts 74.34 and 74.35, or 45 CFR parts 92.32 and 92.33. Property acquired or used under an NIH grant-supported project, including any federally owned property, also is subject to the requirements for internal control specified in 45 CFR part 74.21 or 92.20. Pursuant to 45 CFR part 74.37, equipment (and intangible property and debt instruments) acquired with, or improved with, NIH funds must not be encumbered without NIH approval.

The grantee's management system for equipment must meet the requirements of 45 CFR part 74.34(f) or 92.32, which include the following:

- Records that adequately identify (according to the criteria specified in the regulations) items of equipment owned or held by the grantee and state the current location of each item.
- A physical inventory of the equipment, at least once every 2 years, to verify that the items in the records exist and either are usable and needed or are surplus (a statistical sampling basis is acceptable).
- Control procedures and safeguards to prevent loss, damage, and theft.
- Adequate maintenance procedures to keep the equipment in good condition.
- Proper sales procedures when the grantee is authorized to sell the equipment.

For items of equipment having a unit acquisition cost of $5,000 or more, NIH has the right to require transfer title to the equipment to the Federal government or to an eligible third party named by the NIH awarding IC under the conditions specified in 45 CFR parts 74.34(h) and 92.32, respectively. This right applies to nonexempt property acquired by all types of grantees, including Federal institutions, under all types of grants under the stipulated conditions.

If there is a residual inventory of unused supplies exceeding $5,000 in aggregate fair market value upon termination or completion of the grant and if the supplies are not needed for other federally sponsored programs or projects, the grantee may either retain them for use on other than federally sponsored activities or sell them, but, in either case, the grantee must compensate the NIH awarding IC for its share as a credit to the grant.

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Recipients of NIH grants must not use equipment acquired with grant funds to provide services for a fee to compete unfairly with private companies that provide equivalent services, unless the terms and conditions of the award provide otherwise.

#### 8.3.3.2.3 Revocable License

As permitted under Federal property management statutes and regulations and NIH property management policies, federally owned tangible personal property may be made available to grantees under a revocable license agreement. The revocable license agreement between NIH and the grantee provides for the transfer of the equipment for the period of grant support under the following conditions:

- Title to the property remains with the Federal government.
- NIH reserves the right to require the property to be returned to the Federal government should it be determined to be in the best interests of the Federal government to do so.
- The use to which the grantee puts the property does not permanently damage it for Federal government use.
- The property is controlled and maintained in accordance with the requirements of 48 CFR part 45.5 (the FAR).

## 8.3.4 Procurement System Standards and Requirements

### 8.3.4.1 General

Grantees may acquire a variety of goods or services in connection with a grant-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. States may follow the same policies and procedures they use for procurements from non-Federal funds. All other grantees must follow the requirements in 45 CFR parts 74.40 through 74.48 or 92.36, as applicable, for the purchase of goods or services through contracts under grants. The requirements for third-party activities involving programmatic work are addressed under Consortium Agreements chapter in IIB.

A contract under a grant must be a written agreement between the grantee and the third party. The contract must, as appropriate, state the activities to be performed; the time schedule; the policies and requirements that apply to the contractor, including those required by 45 CFR part 74.48 or 92.36(i) and other terms and conditions of the grant (these may be incorporated by reference where feasible); the maximum amount of money for which the grantee may become liable to the third party under the agreement; and the cost principles to be used in determining allowable costs in the case of cost-type contracts. The contract must not affect the grantee's overall responsibility for the direction of the project and accountability to the Federal government. Therefore, the agreement must reserve sufficient rights and control to the grantee to enable it to fulfill its responsibilities.

When a grantee enters into a service-type contract in which the term is not concurrent with the budget period of the award, the grantee may charge the costs of the contract to the budget period in which the contract is executed even though some of the services will be performed in a succeeding period if the following conditions are met:

- The NIH awarding IC has been made aware of this situation either at the time of application or through post-award notification.

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- The project has been recommended for a project period extending beyond the current year of support.

- The grantee has a legal commitment to continue the contract for its full term.

However, costs will be allowable only to the extent that they are for services provided during the period of NIH support. To limit liability if continued NIH funding is not forthcoming, it is recommended that grantees insert a clause in such contracts of $100,000 or less stipulating that payment beyond the end of the current budget period is contingent on continued Federal funding. The contract provisions prescribed by 45 CFR parts 74.48 and 92.36(i)(2) specify termination provisions for contracts in excess of $100,000.

### 8.3.4.2 Approval Requirements

The procurement standards in 45 CFR parts 74.44 and 92.36(g) allow NIH to require approval of specific procurement transactions under the following circumstances (and provide a mechanism for governmental grantees to be exempt from this type of review):

- A grantee's procurement procedures or operations do not comply with the procurement standards required by those regulations.

- The procurement is expected to exceed the "simplified acquisition threshold" (currently $100,000) (formerly the "small purchase threshold") established by the Federal Property and Administrative Services Act, as amended, and is to be awarded without competition or only one bid or proposal is received in response to a solicitation.

- A procurement that will exceed the simplified acquisition threshold specifies a "brand name" product.

- A proposed award over the simplified acquisition threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.

- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.

When NIH prior approval is required, the grantee must make available sufficient information to enable review. This may include, at NIH discretion, presolicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the applicant or grantee or may be conditioned on the receipt of additional information. Any resulting NIH approval does not constitute a legal endorsement of the business arrangement by the Federal government nor does such approval establish NIH as a party to the contract or any of its provisions.

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#### 8.3.4.3 Contracting with Small Businesses, Minority-Owned Firms, and Women's Business Enterprises

Grantees must make positive efforts to use small businesses, minority-owned firms, and women's business enterprises as sources of goods and services whenever possible. Grantees should take the steps outlined in the applicable administrative requirements (45 CFR part 74.44(b) or 45 CFR part 92.36(e)) to implement this policy.

## 8.4 MONITORING

Grantees are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with NIH requirements. However, to fulfill their role in regard to the stewardship of Federal funds, NIH awarding ICs monitor their grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the grantee, audit reports, site visits, and other information available to NIH. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the grantee at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the grant is administratively closed out and NIH is no longer providing active grant support (see Administrative Requirements—Closeout).

### 8.4.1 Reporting

NIH requires that grantees periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Grantees also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports (SNAPs) and available for all closeout documents (final grant progress reports, final invention statements and certifications, and final financial status reports). When a paper (non-SNAP) non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to OFM (see Financial Reports below) through the eRA Commons eFFR feature unless otherwise indicated in the award's terms and conditions.

Grantees are allowed a specified period of time in which to submit required financial and final progress reports (see 45 CFR parts 74.51 and 74.52, 92.40 and 92.41, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see

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Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

### 8.4.1.1 Non-Competing Continuation Progress Reports

Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The "Non-Competing Continuation Progress Report" (PHS 2590) or equivalent documentation must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information.

The information to be included in the progress report is specified in the PHS 2590 instructions, which also include alternate instructions for awards under SNAP (as described in the next subsection). Forms for paper non-competing continuation progress reports are available at http://grants.nih.gov/grants/funding/2590/2590.htm.

The non-competing Progress Report includes an All Personnel Report on which the grantee must report all individuals who devoted one person month or more effort to the project. The eRA Commons ID must be provided on this report for those who worked on the project in a postdoctoral role.

NIH has centralized the mailing of paper annual non-competing continuation grant progress reports submitted for all NIH ICs. The centralized mailing address is found in Part III. Note paper progress reports are only accepted for the non-SNAP progress reports. All SNAP progress reports must be submitted electronically (see Submitting SNAP Progress Reports below).

Grantees should routinely query and review the list of pending grant progress reports and due dates available at the NIH Web site (http://era.nih.gov/commons/quick_queries/index.cfm#progress). Late submission or receipt of an incomplete grant progress report will result in delaying the issuance and funding of the non-competing continuation award and may result in a reduced award amount.

The progress report for the final budget period of a competitive segment for which a competing continuation application is submitted will be part of that application; however, if an award is not made or the grantee does not submit an application for continued support, a final progress report is required (see Administrative Requirements—Closeout—Final Reports—Final Progress Report).

The NIH awarding IC will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, major alteration and renovation, and non-construction activities.

### 8.4.1.2 Streamlined Non-Competing Award Process

SNAP includes a number of provisions that modify annual progress reports, NoAs, and financial reports.

The NoA will specify whether an award is subject to SNAP. Awards routinely included in SNAP are "K" awards and "R" awards, except R35. Awards excluded from SNAP are those that generally do not have the authority to automatically carry over unobligated balances (centers; cooperative agreements, Kirschstein-NRSA institutional research training grants, non-Fast Track Phase I SBIR and STTR awards), clinical trials (regardless of activity code), P01, R35, and awards to individuals. In addition, specific awards may be excluded from SNAP if:

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- they require close project monitoring or technical assistance, e.g., high-risk grantees, certain large individual or multi-project grants, or grants with significant unobligated balances, or

- the grantee has a consistent pattern of failure to adhere to appropriate reporting or notification deadlines.

#### 8.4.1.2.1 Modified Annual Progress Reports

A SNAP progress report is a streamlined version of the annual progress report requirements. Only limited information is required for each submission.

- IRB and IACUC approval dates are not required as part of each submission. It remains an institutional responsibility to ensure that these reviews are conducted in accordance with all Federal requirements. The Federalwide (human subjects) and Animal Welfare Assurance numbers for the grantee organization are maintained in the Institutional Profile section of the eRA Commons. Actual approval dates must be submitted to NIH upon request.

- No detailed budget information is required; instead, grantees provide answers to the following key questions:

  - **Has there been a change in the "other support" of senior/key personnel since the last reporting period?** If yes, explain the change(s); if no, so state. Specific information is to be provided only if active support has changed. If a previously active grant has terminated and/or if a previously pending grant is now active, the grantee must submit complete Other Support information using the suggested format and instructions found in the PHS 398 application (http://grants.nih.gov/grants/funding/phs398/phs398.html). Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary if support is pending or for changes in the level of effort for active support reported previously.

    Other support information should be submitted only for the PD/PI and all other individuals considered by the PD/PI to be scientifically key to the project. Senior/key personnel are defined as individuals who contribute in a substantive measurable way to the scientific development or execution of the project, whether or not a salary is requested. Do not routinely include Other Support information for Other Significant Contributors, e.g., those that may contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. However, if the level of involvement for an individual previously listed in this category has changed such that they are now considered senior/key personnel, this change should be indicated in this section and Other Support information submitted.

  - **Will there be, in the next budget period, a significant change in the level of effort for the PD/PI(s) or other senior/key personnel named in the NoA from what was approved for this project?** If yes, explain the change(s) (e.g., decreased level of effort from 4.8 CY months to 3.6 CY months); if no, so state. A "significant change" in level of effort is defined in Federal regulations as a 25 percent or greater reduction in time devoted to the project.

  - **Is it anticipated that an estimated unobligated balance (including prior-year carryover) will be greater than 25 percent of the current year's total approved budget?** If yes, the grantee is required to explain why there is a significant balance and

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how it will be spent if carried forward into the next budget period. If no, so state. The "total approved budget" equals the current fiscal year award authorization plus any carryover of funds from a prior year. The numerator equals the total amount available for carryover and the denominator equals the current year's total approved budget.

- If there is a change in performance site or anticipated program income, grantees also must submit the PHS 2590 checklist. If program income is anticipated, the progress report should reflect the estimated amount and source of the income.

Specific instructions for answering the SNAP questions as well as modified requirements of SNAP progress reports are in the PHS 2590 Instructions, http://grants.nih.gov/grants/funding/2590/2590.htm.

The NIH awarding IC will rely on the grantee's assessment of whether significant changes have occurred or will occur in these areas. NIH program or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information will result in a delayed award. Incomplete or inadequate progress reports may be returned for revision and may result in a delay of continued support.

#### 8.4.1.2.2 Modified NoAs

Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and any negotiations, and reduces the information NIH requires to review and approve non-competing continuation awards and to monitor these awards. SNAP NoAs are issued with only total direct and F&A costs awarded for the budget period. While direct costs categorical breakdowns are not awarded, grantees are required to allocate and account for costs by category in accordance with applicable cost principles. Future year commitments on SNAP awards reflect total cost commitments (direct plus F&A costs).

#### 8.4.1.2.3 Modified Financial Reporting Requirements

For awards under SNAP (other than awards to foreign organizations or Federal institutions), an FFR is required only at the end of a competitive segment rather than annually. The FFR must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FSR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout). For awards under SNAP, grantees (other than foreign grantees and Federal institutions) also are required to submit a quarterly FFR to PMS. Foreign organizations and Federal institutions must submit an annual FFR even if an award is under SNAP. (Also see Administrative Requirements—Monitoring—Reporting—Financial Reports.)

#### 8.4.1.2.4 Submitting SNAP Progress Reports

All SNAP progress reports are due no later than 45 days before the next budget start date and must be submitted electronically. Paper submissions are not acceptable, will not be used for consideration for funding, and will not become part of the official file. If a paper SNAP progress report is submitted, grantees will be required to resubmit the information electronically.

The electronic Streamlined Non-Competing Award Process (eSNAP) is a module in the eRA Commons that allows grantees to electronically prepare and submit SNAP progress reports and supporting documentation. eSNAP provides the user with dedicated screens to collect the required SNAP progress

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report information, including appropriate uploads for text documents. Data submitted through eSNAP for Performance Sites and All Personnel is retained in the system for easy update in the future year submission.

When using eSNAP to electronically prepare and submit the SNAP progress report, do not use the PHS 2590 fillable form pages for any file uploads. (Text inserted into the fillable form pages is not saved.)

Electronic routing of eSNAP information to authorizing officials at the applicant institution for review and approval prior to submission to NIH is also a feature of the eSNAP system. In addition, eSNAP provides grantees with the option to delegate to the PD/PI the authority to submit the progress report directly to NIH. This optional authority is managed on a PD/PI basis in the eSNAP system; such authority can be rescinded at any time.

Guidance on eSNAP submission is documented in the eSNAP User Guide found at: http://era.nih.gov/commons/index.cfm. For more information on eSNAP, see https://commons.era.nih.gov/ commons/index.jsp.

### 8.4.1.3 Final Progress Reports

A final progress report is required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. Instructions for the final progress report are found in the PHS 2590. Grantees should also review the information found in Administrative Requirements—Closeout—Final Progress Reports.

### 8.4.1.4 Financial Reports

Two types of financial reports are typically used. Cash transaction data is submitted on a quarterly basis directly to PMS. Expenditure data is submitted directly to the NIH. Historically this data was submitted using 2 separate forms, the SF272 and the SF269. A new form, the SF425 called the Federal Financial Form (FFR), is now used for collecting both types of financial data. For NIH grantees, it is important to note that while the data is now submitted using the same form, there is no change in the actual receipt and processing of data. Cash transaction data continues to be submitted directly to and processed by PMS. Expenditure data continues to be submitted directly to and processed by NIH.

#### 8.4.1.4.1 Cash Transaction Reports

The FFR has a dedicated section to report Federal cash receipts and disbursements. This information is submitted quarterly directly to the PMS using the web-based tool. Quarterly reports are due 30 days the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

#### 8.4.1.4.2 Financial Expenditure Reports

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the grantee organization. NIH is transitioning the reporting of expenditure from the FSR to the FFR. NIH requires all financial expenditure reports to be submitted using the eFSR/FFR system located in the eRA Commons. This includes all initial FSR/FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to NIH. The eRA Commons eFSR/FFR system allows participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH. Paper expenditure reports are not accepted. Expenditure

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data submitted to NIH is initially reviewed and accepted by OFM. NIH IC grants management staff also review these expenditure reports.

Except for awards under SNAP and awards that require more frequent reporting, the FSR/FFR is required on an annual basis. An annual FSR/FFR is required for awards to foreign organizations and Federal institutions, whether or not they are under SNAP. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FSR/FFR will continue to be that of the budget period for the particular grant; however, the actual submission date is now based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date.

For domestic awards under SNAP, in lieu of the annual FSR/FFR, NIH will monitor the financial aspects of grants by using the quarterly cash transaction information submitted directly to PMS using the FFR. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these awards, an FSR/FFR is required only at the end of a competitive segment. It must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FSR/FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FSR/FFR (see Administrative Requirements—Closeout).

Before submitting FSR/FFRs to NIH, grantees must ensure that the information submitted is accurate, complete, and consistent with the grantee's accounting system. When submitting the FSR/FFR through the eRA Commons, the AOR or the individual designated to submit this report on behalf of their institution, certifies that the information in the FSR/FFR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal government. Filing a false claim may result in the imposition of civil or criminal penalties.

***Revised Expenditure Reports.*** NIH requires all financial expenditure reports (domestic and foreign) to be submitted using the electronic FSR/FFR system located in eRA Commons. This includes the initial FFR and any FSR/FFR revisions being submitted or re-submitted to NIH. In some cases the grantee may have to revise or amend a previously submitted FSR/FFR. The revised report should be submitted in the same format as the original; e.g., if the original was an FSR, the revision will also be submitted using the FSR format. When the revision results in a balance due to NIH, the grantee must submit a revised report whenever the overcharge is discovered, no matter how long the lapse of time since the original due date of the report. Revised expenditure reports representing additional expenditures by the grantee that were not reported to NIH within the 90-day time frame may be submitted electronically through the eFSR/FFR system to OFM with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the grantee to preclude similar situations in the future. This should be done as promptly as possible, but no later than 1 year from the due date of the original report, i.e., 15 months following the end of the budget period (or competitive segment for awards under SNAP). If an adjustment is to be made, the NIH awarding IC will advise the grantee of actions it will take to reflect the adjustment.

### 8.4.1.4.3 Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. (See Administrative Requirements—Changes in Project and Budget for NIH approval authorities

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for unobligated balances.) Using the principle of "first in-first out," unobligated funds carried over are expected to be used before newly awarded funds.

Upon receipt of the annual FSR/FFR for awards other than those with authority for the automatic carryover of unobligated balances, the GMO will compare the total of any unobligated balance shown and the funds awarded for the current budget period with the NIH share of the approved budget for the current budget period. If the funds available exceed the NIH share of the approved budget for the current budget period, the GMO may select one of the following options:

- In response to a written request from the grantee, revise the current NoA to authorize the grantee to spend the excess funds for additional approved purposes.
- Offset the current award or a subsequent award by an amount representing some or all of the excess.

#### 8.4.1.4.4 Recipient Reporting of Subrecipient Data and Executive Compensation Information for Federal Funding Accountability and Transparency Act (FFATA)

A component of Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires most recipients of new Federal funds awarded on or after October 1, 2010 to report on subawards/subcontracts/consortiums equal to or greater than $25,000. This includes awards that are initially below $25,000 but subsequent grant modifications result in an award equal to or greater than $25,000.

The FFATA Subaward Reporting System (FSRS) tool can be accessed directly at www.fsrs.gov, and will serve as the collection tool for subaward data which will ultimately be distributed for publication and display on www.USASpending.gov. Grantees are required to register with FSRS, collect the necessary data from subawardees, and file subaward reports by the end of the month following the month in which the prime grantee awards any subaward greater than $25,000.

FFATA specifies the data that should be captured for each prime recipient and first-tier subrecipient of Federal awards, regardless of award type. To promote data consistency and reduce reporting burdens, existing agency data sources will be leveraged to pre-populate reports for prime awardees as well as for subawardees when available. Recipients are responsible for confirming the pre-populated data and providing any additional required information.

Included in these requirements is the need to report the names and total compensation of the five most highly compensated officers of the entity if the entity as part of their registration profile in CCR in the preceding fiscal year: 1) received 80 percent or more of its annual gross revenues in Federal grants, subawards, contracts, and subcontracts; and 2) received $25,000,000 or more in annual gross revenues from Federal grants, subawards, contracts, and subcontracts; and 3) had gross income, from all sources, of $300,000 or more; and 4) the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1). Additionally, recipient organizations may be required to verify the following information in FSRS:

- Organization DUNS number
- Name and Address of organization

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- Parent DUNS number
- CFDA number
- Federal Award Identification Number (FAIN)
- Federal Awarding Agency of the grant

### 8.4.1.5 Invention Reporting

A complete list of the reporting requirements under the Bayh-Dole Act can be found at 37 CFR part 401.14. The requirements also are specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

In addition to complying with Bayh-Dole-related regulations, each NIH competing grant application and non-competing continuation progress report must indicate whether or not any subject inventions were made during the preceding budget period. If inventions were made, the grantee must also indicate whether they were reported.

The grantee also must submit an annual invention utilization report for all subject inventions to which title has been elected and inventions that have been licensed but not patented (research tools). The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

A grantee's failure to comply with invention reporting requirements and/or associated NIH policies on intellectual property and resource sharing may result in the loss of patent rights or a withholding of grant funds or other enforcement actions, including the imposition of special terms and conditions.

Bayh-Dole regulations allow grantees to report inventions electronically (37 CFR part 401.16). NIH strongly supports electronic reporting through an Internet-based system, Interagency Edison (http://iEdison.gov). To meet the objectives of the Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107), grantees should make all reasonable efforts to submit invention reports using iEdison. The system supports confidential transmission of required information and provides a utility for generating reports and reminders of pending reporting deadlines. Further information about the system, including instructions for creating an account needed to submit reports electronically, are on the iEdison site. Grantees also may contact the Division of Extramural Inventions and Technology Resources Branch, OPERA, OER. See Part III for contact information.

## 8.4.2 Record Retention and Access

Grantees generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FSR is submitted. For awards under SNAP (other than those to foreign organizations and Federal institutions), the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Those grantees must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. Foreign organizations and Federal institutions must retain records for 3 years from the date of submission of the annual FSR to NIH. See 45 CFR parts 74.53 and 92.42 for exceptions and qualifications to the 3-year retention requirement (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken).

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Those sections also specify the retention period for other types of grant-related records, including F&A cost proposals and property records. See 45 CFR parts 74.48 and 92.36 for record retention and access requirements for contracts under grants.

These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

### 8.4.3 Audit

An audit is a systematic review or appraisal made to determine whether internal accounting and other control systems provide reasonable assurance of the following:

- Financial operations are properly conducted.
- Financial reports are timely, fair, and accurately.
- The entity has complied with applicable laws, regulations, and other grant terms.
- Resources are managed and used economically and efficiently.
- Desired results and objectives are being achieved effectively.

NIH grantees (other than Federal institutions) are subject to the audit requirements of OMB Circular A-133, as implemented by 45 CFR parts 74.26 and 92.26, or the audit requirements stated in 45 CFR part 74.26(d) and in the NIHGPS (for types of organizations to which OMB Circular A-133 does not directly apply). In general, OMB Circular A-133 requires a State government, local government, or non-profit organization (including institutions of higher education) that expends $500,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts to have an annual audit by a public accountant or a Federal, State, or local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing standards (GAGAS). The audit requirements for foreign grantees and for-profit grantees are addressed in the chapters of this NIHGPS that provide specific requirements for those types of grantees.

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**Exhibit 10. Summary of Audit Requirements**

| Grantee Type | Source of Audit Requirement | Where to Submit Audit Reports |
|---|---|---|
| State & Local Governments | OMB Circular A-133 | Federal Audit Clearinghouse (See contact information in Part III) |
| Colleges & Universities | OMB Circular A-133 | Federal Audit Clearinghouse (See contact information in Part III) |
| Non-Profits | OMB Circular A-133 | Federal Audit Clearinghouse (See contact information in Part III) |
| Hospitals | OMB Circular A-133 | Federal Audit Clearinghouse (See contact information in Part III) |
| For-Profits | 45 CFR part 74.26(d) | National External Audit Review Center (See contact information in Part III) |
| Foreign | NIH Grants Policy Statement (same as For-Profits) | (same as For-Profits) |

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When a grantee procures audit services, the procurement must comply with the procurement standards of 45 CFR part 74 or 92, as applicable, including obtaining competition and making positive efforts to use small businesses, minority-owned firms, and women's business enterprises. Grantees should ensure that comprehensive solicitations made available to interested firms include all audit requirements and specify the criteria to be used for selection of the firm. Grantees' written agreements with auditors must specify the rights and responsibilities of each party.

OMB Circular A-133 explains in detail the scope, frequency, and other aspects of the audit. Some highlights of this Circular are as follows:

- Covered organizations expending $500,000 or more per year in Federal awards are required to have an audit performed in accordance with the Circular. However, if the awards are under one program, the organization can have either a single organization-wide audit or a program-specific audit of the single program, subject to the provisions of section 235 of the Circular. NIH's research awards may not be considered a single program for this purpose. Covered organizations expending less than $500,000 in any year are exempt from these audit requirements in that year but must have their records available for review as required by Administrative Requirements—Monitoring—Record Retention and Access.

- The reporting package must contain the following:

    - Financial statements and schedule of expenditures of Federal awards.
    - Independent auditor's report, including an opinion on the financial statements and the schedule of expenditures of Federal awards, a report on compliance and internal control over financial reporting, and a report on compliance with requirements applicable to each major program and on internal control over such compliance requirements.
    - A schedule of findings and questioned costs.

  - If applicable, a summary of prior audit findings and a corrective action plan.

- An audit under OMB Circular A-133 is in lieu of a financial audit of individual Federal awards. However, Federal agencies may request additional audits necessary to carry out their responsibilities under Federal law or regulation. Any additional audits will build upon work performed by the independent auditor.

- The data collection form and copies of the reporting package must be submitted to the FAC at the address provided in Part III.

If the schedule of findings and questioned costs discloses an audit finding related to an HHS or NIH award or if the schedule of prior audit findings reports the status of any audit finding relating to an HHS or NIH award, the FAC will provide copies of the audit report to NEARC, OIG, HHS. NEARC will, in turn, distribute them within HHS for further action, as necessary. Audit reports should not be sent directly to the GMO.

Recipients must follow a systematic method for ensuring timely and appropriate resolution of audit findings and recommendations, whether discovered as a result of a Federal audit or a recipient-initiated audit. Grantees usually are allowed 30 days from the date of request to respond to the responsible audit resolution official (Action Official) concerning audit findings. Failure to submit timely responses may result in cost disallowance or other actions by NIH or HHS. At the completion of the audit resolution process, the grantee will be notified of the Action Official's final decision. The grantee may appeal this decision if the adverse determination is of a type covered by the NIH or HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures). Refunds owed to the Federal government as a result of audit disallowances must be made in accordance with instructions issued by the Action Official or OFM.

It is imperative that grantees submit required OMB Circular A-133 audits within the time limits specified in the Circular. If grantees are delinquent in complying with the provisions of the Circular, HHS or NIH will impose sanctions that may result in the loss of Federal funds. No audit costs will be allowed either as F&A costs or direct costs to Federal awards if the required audits have not been completed or have not been conducted in accordance with the provisions of OMB Circular A-133.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of audit costs.

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## 8.5 ENFORCEMENT ACTIONS

A grantee's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more enforcement actions, depending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the grantee an opportunity to correct the deficiencies before taking enforcement action unless public health or welfare concerns require immediate action. However, even if a grantee is taking corrective action, NIH may take proactive action to protect the Federal government's interests, including placing special conditions on awards or precluding the grantee from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

## 8.5.1 Modification of the Terms of Award

During grant performance, the GMO may include special conditions in the award to require correction of identified financial or administrative deficiencies. When the special conditions are imposed, the GMO will notify the grantee of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. See 42 CFR part 52.9 and 45 CFR part 74.14 or 92.12.

The NIH awarding IC also may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform. In that case, the awarding IC may request that the grantee designate a new PD/PI or other named senior/key personnel.

The decision to modify the terms of an award—by imposing special conditions, by withdrawing approval of the PD/PI or other named senior/key personnel, or otherwise—is discretionary on the part of the NIH awarding IC.

## 8.5.2 Suspension, Termination, and Withholding of Support

If a grantee has failed to materially comply with the terms and conditions of award, NIH may suspend the grant, pending corrective action, or may terminate the grant for cause. The regulatory procedures that pertain to suspension and termination are specified in 45 CFR parts 74.61 and 74.62, and in part 92.43.

NIH generally will suspend (rather than immediately terminate) a grant and allow the grantee an opportunity to take appropriate corrective action before NIH makes a termination decision. NIH may decide to terminate the grant if the grantee does not take appropriate corrective action during the period of suspension. NIH may terminate—without first suspending—the grant if the deficiency is so serious as to warrant immediate termination or public health or welfare concerns require immediate action. Termination for cause may be appealed under the NIH and HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures). Pending the outcome of an appeal or other action by the grantee, NIH may award a replacement grant for a limited period of time (up to 18 months) without competition.

A grant also may be terminated, partially or totally, by the grantee or by NIH with the consent of the grantee. If the grantee decides to terminate a portion of a grant, NIH may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, NIH will advise the grantee of the possibility of termination of the entire grant and allow the grantee to withdraw its termination request. If the grantee does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire grant for cause.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of termination costs. Allowability of these costs does not vary whether a grant is terminated for cause by NIH, terminated at the request of the grantee, or terminated by mutual agreement.

Withholding of support is a decision not to make a non-competing continuation award within the current competitive segment. Support may be withheld for one or more of the following reasons:

- Adequate Federal funds are not available to support the project.
- A grantee failed to show satisfactory progress in achieving the objectives of the project.

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- A grantee failed to meet the terms and conditions of a previous award.
- For whatever reason, continued funding would not be in the best interests of the Federal government.

If a non-competing continuation award is denied (withheld) because the grantee failed to comply with the terms and conditions of a previous award, the grantee may appeal that determination.

### 8.5.3 Other Enforcement Actions

Depending on the nature of the deficiency, NIH may use other means of obtaining grantee compliance. Other options available to NIH include, but are not limited to, temporary withholding of payment or other actions specified at 45 CFR part 74.62 or 92.43, conversion from an advance payment method to a reimbursement method, suspension or debarment under 45 CFR part 76, and other available legal remedies, such as civil action. Suspension under 45 CFR part 76, implementing E.O.s 12549 and 12689, "Debarment and Suspension," is a separate action from the "suspension" of an award as a post-award remedy, as described in Suspension, Termination, and Withholding of Support above. The subject of debarment and suspension as an eligibility criterion is addressed in Completing the Pre-Award Process—Determining Eligibility of Individuals and Public Policy Requirements and Objectives—Debarment and Suspension.

### 8.5.4 Recovery of Funds

NIH may identify and administratively recover funds paid to a grantee at any time during the life cycle of a grant. Debts may result from cost disallowances, recovery of funds, unobligated balances, unpaid share of any required matching or cost sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances. NIH may identify and initiate debt collection activities at any time during the life cycle of a grant.

### 8.5.5 Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR parts 900-904), which are implemented for HHS in 45 CFR part 30. NIH is required to collect debts due to the Federal government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by grantees.

When NIH determines the existence of a debt under a grant, written debt notification will be provided to the grantee. Unless otherwise specified in law, regulation, or the terms and conditions of the award, debts are considered delinquent if they are not paid within 30 days from the date the debt notification is mailed to the grantee. Delinquent debts are subject to the assessment of interest, administrative cost charges, and penalties. The interest on delinquent debts accrues on the amount due beginning on the date the debt notification is mailed to the grantee.

If a grantee appeals an adverse monetary determination under 42 CFR part 50, Subpart D, or 45 CFR part 16, interest will accrue but assessment will be deferred pending a final decision on the appeal. If the appeal is not successful, interest will be charged beginning with the date the debt notification was mailed to the grantee, not the date of the appeal decision. Interest charges will be computed using the prevailing rate in effect on the date the debt notification is mailed, as specified by the Department of the Treasury and 45 CFR part 30.13(a)(2). See http://www.hhs.gov/of/library/policy/debt/debtcoll.html.

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# 8.6 CLOSEOUT

The requirement for timely closeout is a grantee responsibility. Failure to submit timely and accurate closeout documents may affect future funding to the organization. NIH may impose sanctions on institutions that fail to correct recurring reporting problems. Such sanctions may include, but are not limited to, corrective actions, removal of authorities, and/or delay or withholding of further awards to the project or program. NIH will close out a grant as soon as possible after expiration if the grant will not be extended or after termination as provided in 45 CFR parts 74.71 through 74.73 and in 45 CFR part 92.50. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due the grantee or NIH. Closeout of a grant does not automatically cancel any requirements for property accountability, record retention, or financial accountability. Following closeout, the grantee remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the Federal government may recover amounts based on the results of an audit covering any part of the period of grant support.

Grantees must submit a final FSR, final progress report, and Final Invention Statement and Certification within 90 calendar days of the end of grant support.

## 8.6.1 Final Federal Financial Report

A final FFR is required for

- any grant that is terminated,
- any grant that is transferred to a new grantee, or
- any award, including awards under SNAP, which will not be extended through award of a new competitive segment.

Grantees are required to electronically submit the final FFR through the eRA Commons (https://commons.era.nih.gov/commons). The final FFR must cover the period of time since the previous FSR/FFR submission or, for awards under SNAP, the entire competitive segment or as much of the competitive segment as has been funded before termination. Final FFRs must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the Federal share of net outlays reported on the final FFR and the net cash disbursements reported to PMS on the Federal cash section on the FFR. Unobligated funds must be returned to NIH or must be reflected by an appropriate accounting adjustment in accordance with instructions from the GMO or from the payment office. For those organizations receiving their funds through PMS, final reports, as specified by PMS, must be submitted to that office. It is the grantee's responsibility to reconcile reports submitted to PMS and to the NIH awarding IC. Withdrawal of the unobligated balance following expiration or termination of a grant is not considered an adverse action and is not subject to appeal (see Administrative Requirements—Enforcement Actions—Recovery of Funds).

When the submission of a revised final FFR results in additional claims by the grantee, NIH will consider the approval of such claims subject to the following minimum criteria:

- The grantee must indicate why the revision is necessary and explain and implement internal controls that will preclude similar occurrences in the future.
- The charge must represent otherwise allowable costs under the provisions of the grant.

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- There must be an unobligated balance for the budget period sufficient to cover the claim.
- The funds must still be available for use.
- NIH must receive the revised FSR within 15 months of its original due date.

### 8.6.2 Final Progress Report

A final progress report is required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. If a competitive renewal (Type 2) application has been submitted, whether funded or not, the progress report contained in that application may serve in lieu of a separate final progress report. Otherwise, a final progress report should be prepared in accordance with the requirements in the PHS 2590 instructions and any specific requirements set forth in the terms and conditions of the award. At a minimum, the final progress report should include a summary of progress made toward the achievement of the originally stated aims, a list of significant results (positive or negative), and a list of publications. Grantees should also report additional information required by the awarding IC in program-specific final progress report instructions. The final progress report also should address the following when applicable:

- Report on the inclusion of gender and minority study subjects (using the gender and minority inclusion table as provided in the PHS 2590).
- Where appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see Public Policy Requirements and Objectives—Inclusion of Children as Subjects in Clinical Research).
- Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed.
- Publications that were authored or co-authored by the PD/PI and arose from the award must include the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.
- If there are any other specific requirements set forth in the terms and conditions of the award, they must be addressed in the final progress report as well.

### 8.6.3 Final Invention Statement and Certification

The grantee must submit a Final Invention Statement and Certification (HHS 568), whether or not the funded project results in any subject inventions, and whether or not inventions were previously reported. The HHS 568 must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, and it must be signed by an AOR. The completed form should cover the period from the original effective date of support through the date of expiration or termination or the award, and it should be submitted to the NIH awarding IC. If there were no inventions, the form must indicate “None.” For certain programs (activity codes = C06, R13, R25, S15, Ts, and Fs), the Final Invention Statement and Certification is not currently required. For questions, the grantee should contact NIH awarding IC for specific instructions.

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When invention reporting is required, the HHS 568 does not relieve the responsible party of the obligation to assure that all inventions are promptly and fully reported directly to the NIH, as required by terms of the award. Copies of the HHS 568 form are available on the iEdison Web site at http://iEdison.gov and at http://grants.nih.gov/grants/forms.htm.

### 8.6.4 Submission of Closeout Documents

Use of the Closeout feature in the eRA Commons is strongly encouraged. Submission of non-financial closeout documents (such as the final progress report and HHS 568 Final Invention Statement and Certification) not submitted through the eRA Commons may be e-mailed as PDF attachments to the NIH Central Closeout Center. Paper copies of the final progress report and HHS 568 may be faxed or mailed to the NIH Central Closeout Center at the contact information provided in Part III.

## 8.7 GRANT APPEALS PROCEDURES

HHS permits grantees to appeal to the DAB certain post-award adverse administrative decisions made by HHS officials (see 45 CFR part 16). NIH has established a first-level grant appeal procedure that must be exhausted before an appeal may be filed with the DAB (see 42 CFR part 50, Subpart D). NIH will assume jurisdiction for the following adverse determinations:

- Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of award or for failure of the grantee otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
- Determination that an expenditure not allowable under the grant has been charged to the grant or that the grantee has otherwise failed to discharge its obligation to account for grant funds.
- Denial (withholding) of a non-competing continuation award for failure to comply with the terms of a previous award.
- Determination that a grant is void (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

The formal notification of an adverse determination will contain a statement of the grantee's appeal rights. As the first level in appealing an adverse determination, the grantee must submit a request for review to the NIH official specified in the notification, detailing the nature of the disagreement with the adverse determination and providing supporting documents in accordance with the procedures contained in the notification. The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of the grantee's position with respect to such issue(s) and the pertinent facts and reasons in support of the grantee's position. In addition to the required written statement, the grantee shall provide copies of any documents supporting its claim. The grantee's request to NIH for review must be submitted no later than 30 days after the written notification of the adverse determination is received; however, an extension may be granted if the grantee can show good cause why an extension is warranted (42 CFR part 50.406).

If the NIH decision on the appeal is adverse to the grantee or if a grantee's request for review is rejected on jurisdictional grounds, the grantee then has the option of submitting a request to the DAB for a further review of the case in accordance with the provisions of 45 CFR part 16. A prospective appellant must submit a notice of appeal to the DAB within 30 days after receiving the final NIH decision.

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A grantee may not submit an appeal directly to the DAB because the DAB will review only those appeals that have been reviewed and acted on by NIH.

In addition to the adverse determinations indicated, the DAB is the single level of appeal for disputes related to the establishment of F&A cost rates, research patient care rates, and certain other cost allocations used in determining amounts to be reimbursed under NIH grants (e.g., cost allocation plans negotiated with State or local governments and computer, fringe benefit, and other special rates). The determination leading to such disputes may be made by an HHS official other than the GMO and may affect NIH grants as well as other HHS grants.

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# 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 IIA because of the type of grant, grantee, or grant-supported activity. Each chapter of IIB specifies how the coverage relates to that in IIA and must be used in conjunction with IIA to determine all of the applicable terms and conditions of a covered type of activity, grantee, or award.

This Subpart contains the following chapters:

- Multiple Program Director/Principal Investigator Applications and Awards
- Construction, Modernization, or Major Alteration and Renovation of Research Facilities (this chapter also includes requirements for specified A&R activities under non-construction grants)
- Individual Fellowships and Institutional Research Training Grants (also termed "fellowships" and "training grants") under the Kirschstein-NRSA program
- Career Development Awards
- Modular Applications and Awards
- Support of Scientific Meetings (Conference Grants)
- Consortium Agreements
- Grants to Foreign Institutions, International Organizations, and Domestic Grants with a Foreign Component
- Grants to Federal Institutions and Payments to Federal Employees Under Grants
- Grants to For-Profit Organizations
- Research Patient Care Costs.

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# 9 MULTIPLE PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR APPLICATIONS AND AWARDS

## 9.1 GENERAL

Multiple Program Director/Principal Investigator (multiple PD/PI) awards are an opportunity for multidisciplinary efforts and collaboration through a team of scientists under a single grant award. All PD/PIs share equally the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the applicant organization, or as appropriate to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one PD/PI on an application or award

diminishes neither the responsibility nor the accountability of any individual PD/PI. The applicant/grantee organization is responsible for securing and retaining the required written assurance signatures from each identified PD/PI on all applications, post-submission information, progress reports, and post-award prior approval requests.

NIH implementation of Multiple PD/PIs is in accordance with the January 4, 2005 Office of Science Technology Policy directive to Federal research agencies. Additional information on Agency implementation plans can be found at: http://rbm.nih.gov/toolkit.htm. NIH also maintains a Web site dedicated to the Multiple PD/PI initiative at: http://grants.nih.gov/grants/multi_pi/index.htm.

## 9.2 APPLICABILITY

Applications submitted electronically through Grants.gov for most award mechanisms permit multiple PD/PIs, with the exception of awards for which multiple PD/PIs would not be appropriate such as individual fellowship and career awards, dissertations grants (R36), Shared Instrumentation Grants (S10), and Pioneer Awards (DP1). Applications submitted on the paper PHS 398 Grant Application may only include multiple PD/PIs if the option is clearly specified in the Funding Opportunity Announcement. SBIR/STTR applicants may use the multiple PD/PI option; refer to the SBIR/STTR multiple PD/PI section for specific requirements affecting small business concerns.

## 9.3 APPLICATION REQUIREMENTS

The decision to submit a multiple PD/PI application is that of the applicant organization and the PD/PIs, and should be consistent with the scientific goals of the project. A single applicant organization may designate multiple PD/PIs from the applicant organization or may designate multiple PD/PIs from multiple institutions. Multiple organizations may not submit the same multiple PD/PI application.

All PD/PIs must be qualified and have appropriate expertise to serve as a PD/PI and the appropriate level of authority and responsibility to direct the project or program as part of the leadership team. Each PD/PI must have a defined role on the project. There is no limit on the number of PD/PIs that may be designated, and no minimum person months requirement, except STTR applicants where each PD/PI must commit a minimum of 1.2 calendar months (10%) effort (see Grants to For-Profit Organizations—SBIR and STTR Programs—Multiple PD/PI Applications and Awards).

***Contact PD/PI.*** The applicant organization must designate one of the PD/PIs as the Contact PD/PI to serve as a primary point of contact. The Contact PD/PI must be listed first on the application and must be associated with the applicant organization. The Contact PD/PI is responsible for communication between the PD/PIs and the NIH, but has no special authorities or responsibilities within the leadership team. Responsibilities of the Contact PD/PI may include communication between the leadership team and the NIH, assembly of the application materials, and coordination of progress reports. On complex projects the Contact PD/PI may request additional effort for coordination responsibilities if necessary.

***eRA Commons Registration Required.*** All PD/PIs must have established eRA Commons accounts with a PI role prior to application submission. When multiple PD/PIs are at different organizations, all organizations must also be registered in the eRA Commons. If the contact PD/PI is at a different institution from the applicant organization, then the applicant organization must also affiliate the contact PD/PI with their institution. Beyond the contact PD/PI, it is not necessary for all other PD/PIs to be affiliated with the applicant organization.

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***Leadership Plan.*** All multiple PD/PI applications are required to include a Leadership Plan. The purpose of the Leadership Plan is to facilitate and enhance scientific productivity and establish a decision-making process. The Plan must describe a rationale for choosing the multiple PD/PI approach. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs, including responsibilities for human or live vertebrate animal subject studies as appropriate.

The Leadership Plan may include a description of allocation of resource or funds to specific components of the project, or to individual PD/PIs either at the applicant organization or at other organizations. In the event of an award, NIH will reference to the requested allocation in an IC-specific term and condition in the NoA. The grantee institution may then set up special accounts to reflect the information in the term. The term will not imply that the institution must implement the allocation, and NIH will not track the requested allocation.

***New Investigators (Including Early Stage Investigators).*** Multiple PD/PI applications may designate senior and new investigators, including early stage investigators. However, the application will only be considered a new investigator application when all of the PD/PIs meet the NIH definition of new investigator, and will only be considered an early stage investigator application when all of the PD/PIs meet the NIH definition of early stage investigator. For the purposes of classification as a new investigator, serving as a PD/PI on a multiple PD/PI grant is equivalent to serving as a PD/PI on a single PD/PI grant. Thus, if a new investigator successfully competes as a PD/PI on a multiple PD/PI grant, she or he no longer qualifies as a new (or early stage) investigator on a single PD/PI application.

***Multi-Project Applications.*** Assuming the FOA for Multi-project applications (e.g., P01, P30) specifically allows multiple PD/PIs, applications may include multiple PD/PIs for subprojects as well as the entire program.

***Budgets.*** In general, multiple PD/PI applications will submit a single budget for the entire project. This applies to both modular and detailed budgets. When determining if a modular budget should be submitted, the $250,000 threshold is for the entire project, not per PD/PI. When multiple PD/PIs are at different institutions, the standard instructions for submitting consortium budgets apply. Applicants can choose to include budget allocation information for specific PD/PIs as part of the Leadership Plan. In the event of an award, the requested allocations may be reflected in a term in the NoA (see Leadership Plan above).

***Renewal or Resubmission Applications.*** A renewal or resubmission application may change from a single PD/PI to multiple PD/PIs; however, the applicant must provide a rationale for the change in the Introduction, and include the required Leadership Plan in the application. Likewise, a previously submitted multiple PD/PI application may change to a single PD/PI application in a renewal or resubmission; the applicant must provide a rationale for the change in the Introduction.

***Competing Revision Applications.*** A competing revision application to an existing Multiple PD/PI grant must be submitted using the same Contact PD/PI as the parent grant, and may propose changes in the Leadership Plan or in the composition of the leadership (by adding or removing PD/PIs), and should provide a rationale for any such changes. A competitive revision to a single PD/PI grant may be submitted proposing multiple PD/PIs provided a Leadership Plan is also included.

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## 9.4 APPLICATION REVIEW AND AWARD

The review criteria applied to multiple PD/PI applications are the same criteria applied to single PD/PI applications and each application will be evaluated on its own merit (see The Peer Review Process in Part I). Peer reviewers will consider each PD/PI's qualifications and identified role in the project. The leadership approach will be used to facilitate understanding of the complexities of the science and the management of the project. The quality of the Leadership Plan will be considered as part of the assessment of the overall approach, and incorporated into the scientific and technical merit determination. Peer reviewers will not recommend that individual PD/PIs be removed; however, reviewers may recommend deletion of the specific aims and budget of a PD/PI, which would effectively remove the PD/PI's effort.

All PD/PIs are listed on the Summary Statement, in the NoA, and in NIH databases.

## 9.5 POST-AWARD ADMINISTRATION

If multiple PD/PIs are from multiple organizations, NIH will generally issue the award to the applicant organization which will administer the award using consortium or subaward arrangements in accord with the Consortium Agreements chapter. Budgets, including F&A costs associated with subawards, will be determined according to existing policy. Changes in the allocation and the size of subawards will be handled in the same way as single PD/PI awards.

Responsibility for all required reports is shared by the PD/PIs and the grantee institution. Only one of each required report should be submitted. Although all PD/PIs are responsible for the content of all reports, only the Contact PD/PI may upload information in the eRA Commons. As with most other Commons features, only the grantee Signing Official may submit the reports to NIH, including closeout reports (final invention statement, progress report and financial status report).

Requests for administrative supplements must be submitted from an authorized official at the grantee organization and include the grant number and name of the Contact PD/PI in the request. For all applications, post-submission information, progress reports, and prior approval requests, the grantee organization remains responsible for securing and retaining the required written assurance signatures from each identified PD/PI.

A change in Contact PD/PI may be designated in a non-competing continuation progress report; the Contact PD/PI must be a member of the existing peer reviewed leadership team and associated with the grantee organization. Revision of the Leadership Plan during the project period may be accomplished through a joint decision of the PD/PIs and reported in a non-competing continuation progress report.

Additional PD/PIs may not be added to an existing award. Addition of PD/PIs, either to a single PD/PI award or to a multiple PD/PI award requires peer review of the Leadership Plan and may only be proposed in a new or renewal application.

All existing prior approval requirements apply to multiple PD/PI awards, including the change in status of any one of the PD/PIs, refer to Administrative Requirements—Prior Approval Requirements in IIA. If a PD/PI withdraws from the grant or is no longer able to work on the project, NIH will evaluate the request considering the project as a whole, including the impact on the scope of work and Leadership Plan.

If the Contact PD/PI changes institutions, the grantee institution will need to consider options. Since it is required that the Contact PD/PI be affiliated with the grantee institution in the Commons, the institution

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may choose to designate another PD/PI as the Contact. Another option would be to relinquish the grant and allow it to be transferred. Contact PD/PIs considering transferring should consult with the NIH awarding IC early in the process to discuss options.

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# 10 CONSTRUCTION, MODERNIZATION, OR MAJOR ALTERATION AND RENOVATION OF RESEARCH FACILITIES

## 10.1 GENERAL

The chapter 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 acquisition and off-site improvements). The construction of shell space is not allowable as a construction activity since shell space does not provide usable space for research activities. Expansion, new construction, or activities that would change the "footprint" of an existing facility (e.g., relocation of existing exterior walls, roofs, or floors, attachment of fire escapes) is considered construction.

- ***Modernization.*** A subset of construction as defined above where alteration, renovation, remodeling, improvement, expansion, and/or repair of an existing building and the provision of equipment necessary to make the building suitable for use for the purposes of a particular program. The entire purpose of the modernization grant is to modernize biomedical research facilities and not to support the conduct of any research.

- ***Major Alteration and Renovation (A&R).*** An A&R project under a grant whose primary purpose is other than construction or modernization, including a project involving modernization, improvement or remodeling, exceeding $500,000 in direct costs awarded for the project. Major A&R may include improvement, conversion, rearrangement, rehabilitation or remodeling. Major A&R does not apply to minor alterations, renovations or repairs funded under a research project grant or alterations or renovations funded under an NIH center grant. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants.

To provide support for these types of activities, an IC must have specific statutory authority allowing construction or modernization. Even if NIH has this authority, a grantee may not incur costs for any of these activities unless NIH specifically authorizes such costs.

NIH generally solicits applications, and makes awards, for construction or modernization under grants or cooperative agreements specifically for that purpose. The grantee retains the primary responsibility for the project as a whole, including all phases of design and construction. When needed, NIH staff provides technical assistance in designing, constructing, and commissioning the facility and coordinating collaboration with other IC-funded construction activities. Under cooperative agreements, there is substantial scientific/programmatic staff involvement during the performance of the activity.

In addition, an applicant/grantee may propose to undertake an A&R project(s) under a grant whose primary purpose is other than construction or modernization. NIH characterizes these A&R projects as "minor" or "major," depending on the type of activity proposed and the cost of the project. An A&R project under a grant whose purpose is other than construction or modernization that costs $500,000 or less in direct costs is generally treated as minor A&R. If a recipient believes a post-award change that would result in an A&R project of $500,000 or less in direct costs meets the definition of construction, it should notify the GMO in order for the IC to determine whether it is construction and whether the IC has

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the necessary statutory authority. The requirements that apply to minor A&R projects are addressed in IIA. Minor A&R projects are not required to satisfy all of the requirements of this chapter. Major A&R projects are subject to the requirements of this chapter as indicated.

Except where indicated, the requirements in this chapter apply to NIH grant-supported construction or modernization in lieu of the requirements in IIA. For major A&R projects, this chapter applies to the A&R activity only and IIA pertains to the other grant-supported activities under the same award, if any. However, there may be areas of overlap (e.g., a rebudgeting action that causes a minor A&R project to become a major A&R project). See Exhibit 11 for a summary of the requirements specified in this chapter and their potential applicability to construction, modernization, or major A&R.

This chapter addresses all aspects of grant-supported construction, modernization, and major A&R from application through closeout. Due to the size and complexity of these activities, this chapter describes in detail requirements and recipient responsibilities related to procurement of construction services (see Procurement Requirements for Construction Services below). Applicants and grantees also should refer to the construction grant program regulations (42 CFR part 52b), which, by their terms, apply to construction and modernization grants as well as major A&R under a research grant mechanism; 45 CFR part 74 or 92; and program guidelines, as applicable. Questions concerning construction or modernization grants or major A&R requirements or policies should be directed to the GMO or other official designated in the NoA.

### 10.1.1 Eligibility

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

### 10.1.2 Funding Opportunity Announcements

Construction grant applicants are required to apply in response to a specific FOA. RFAs generally are used to solicit construction or modernization grant applications. PAs also may be issued to solicit construction or modernization grant applications for ongoing programs for which applications may be submitted under multiple cycles or years.

In addition to the FOA, NIH awarding ICs also may develop program guidelines that include detailed policy and procedural information applicable to specific construction and modernization grant programs/activities. Any program-specific requirements will be included in or referenced in the FOA and NoA. Applicants should consult the FOA and program guidelines, if any, when applying for construction or modernization grants.

### 10.1.3 Application Review and Award

Construction and modernization grant applications and applications requesting funding for a major A&R project are subject to peer review. Specific review criteria are included in the FOA.

Construction and modernization grants usually involve a single award, covering more than one year, made on the basis of an application for the entire project. Incremental funding (budget periods) within a project period normally is not used for construction or modernization grants and funding may be limited by the requirements of Federal appropriations law which may limit NIH's ability to approve no-cost

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extensions. Grantees must consult with the GMO if it is expected that the construction or modernization activity is unlikely to be concluded within the project period specified in the NoA.

Unlike other grants awarded by NIH, under which a grantee's signature is not required to indicate acceptance of an award, under construction and modernization grants, the AOR must sign the NoA and return it to the GMO to indicate acceptance of the terms and conditions of award.

### 10.1.4 Title to Site

NIH expects that the applicant holds (or will hold) fee simple title (i.e., absolute ownership of real property or absolute title to land, free of any claims against the title) to the property or other estate or interest in the site (e.g., leasehold interest) on which the construction, modernization, or major A&R is performed. NIH will determine whether an applicant meets this requirement as part of the administrative review of an application.

The applicant must include with the application a legal opinion describing the interest the applicant has in the performance site. The legal opinion should describe any mortgages or other foreclosable liens on the property, including the principal amount of the mortgage (and rate of interest); the dates of the mortgage; the terms and conditions of repayment; the appraised value of the property; and any provisions designed to protect the Federal interest in the property.

### 10.1.5 Matching Requirement

The requirements for grantees to share in the cost of the project are set forth in 42 CFR part 52.b.6, *What is the rate of federal financial participation?* Unless otherwise specified by statute, the rate of federal financial participation in a construction project cannot be more than 50 percent of allowable construction or modernization costs. The NIH can waive this requirement; however, it is not automatic and must be requested from the IC prior to application submission.

Matching may be in the form of allowable costs incurred by the grantee or a contractor under the grant. NIH generally does not allow grantees to use the value of third party in-kind contributions as a source to meet a matching requirement; however, the GMO may allow third party in-kind contributions included in the application budget on an exception basis. Third party in-kind contributions are the value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property and the value of goods and services directly benefiting and specifically identifiable to the project or program. To be allowable as matching, costs and in-kind contributions (if authorized) must meet the allowability and documentation requirements of 45 CFR part 74.23 or 92.24, as applicable. Costs and third party in-kind contributions claimed as matching also are subject to the requirements in IIA that apply to the expenditure of NIH funds.

The source and amount of funds proposed by an applicant to meet a matching requirement must be identified in the application. The applicant also will be required to demonstrate that the funds are committed or available at the time of, and for the duration of, the award. Exception to "cash on hand" will require negotiation with the NIH prior to award. This may take the form of an assurance, as specified by the NIH awarding IC. The amount of NIH (Federal) funds awarded, combined with the non-Federal share, will constitute the total approved budget as shown in the NoA. The prior approval and other dollar thresholds contained in this chapter are based on the total approved budget unless otherwise specified. Downward adjustments to the matching requirement after award are a prior approval action. If NIH approval is not received in advance it is considered a violation of the terms and conditions of the construction award and may warrant enforcement action.

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In addition to sharing in the costs of a construction or modernization grant, the grantee must ensure the availability of sufficient funds for operation (or continued operation) of the facility when construction or modernization is completed to allow the effective use of the facility for the grant-supported purposes.

# 10.2 PROCUREMENT REQUIREMENTS FOR CONSTRUCTION SERVICES

## 10.2.1 General

Construction, modernization, and major A&R activity usually is carried out through one or more contracts under the grant. Therefore, the circumstances of the procurement are critical to the successful completion of the grant-supported project. Grantee procurement must comply with the requirements specified in 45 CFR parts 74.40 through 74.48 or in part 92.36, as applicable. Grantees must use only those contracting methods that will:

- Ensure that all qualified contractors are given an opportunity to bid or propose and to have their bids/proposals fairly considered.

- Ensure that the contract(s) will result in the completion of a facility—ready for occupancy—that conforms to the design and specifications approved by NIH (or any appropriate modification thereof also approved by NIH), at a cost that is within the owner's ability to pay.

Unless otherwise authorized by NIH, all work associated with NIH grant-supported construction, modernization, or major A&R must be procured by formal advertising, resulting in lump-sum, fixed-price contracts. NIH may authorize other procurement methods and other types of contracts when sealed bidding is impractical. The grantee must obtain NIH approval of plans and specifications both before bids or proposals are solicited and prior to the award of the contract. The grantee must ensure that the project is completed in accordance with the approved plans and specifications or secure NIH approval of any changes that materially alter the scope or costs of the project, use of space, or functional layout.

The two basic means of ensuring that a contract can be awarded at, or very near, the budgeted amount are accurate cost estimating and the use of bid alternates.

A precise description of the scope of work, specifications, materials, and construction techniques will facilitate accurate cost estimating by the grantee and, ultimately, the responsive bidders. The description of the scope of work is especially important when multiple contracts will be awarded in support of the same project, because each contractor must know exactly what is involved in the portions of the job being bid.

Where practical, the grantee may request in the invitation for bids, alternates to the base bid which are keyed to specified, and explicitly stated, changes in the project scope, materials, or construction techniques. The invitation may contain either additive alternates (adjustments increasing the amount of the base bid), or deductive alternates (adjustments reducing the amount of the base bid), or both. Additive alternates will make it possible to incorporate necessary features that otherwise would not have been included in the project. Alternates that are selected may be included in determining the low aggregate bid.

If, notwithstanding the use of deductive alternates, all bids exceed the funds available, the grantee may:

- Decline to award the contract(s) and instead, after NIH approval, issue a revised invitation for bids containing changes in the bid documents or other factors affecting price.

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- Negotiate with the low bidder. All changes in design and specifications resulting from such negotiations must be approved by NIH. If the low bidder refuses to negotiate, negotiations may be entered into with the next lowest bidder. If efforts to negotiate are unsuccessful, all bids must be cancelled and the project rebid.

If the NIH-supported project is less than the entire facility or project, the grantee must obtain bids or proposals that provide the costs for that portion of the total job that will be paid by NIH funds or any required matching. This may be done in one of the following ways:

- If the project consists of more than one building or site and can be divided for purposes of obtaining a price or cost estimate and for carrying out the construction or modernization, showing the cost for each building or site , or

- If the project is a single site or contains common space and cannot be divided for pricing and construction or modernization purposes, identifying or prorating the applicable costs or price.

### 10.2.2 Liquidated Damages

Invitations for bids must stipulate a time for completion of the project, expressed either in calendar days or as a fixed date, for each prime contract to be awarded under the project.

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

## 10.3 ALTERNATE CONTRACTING METHODS

The use of a contracting method other than formal advertising, including the use of construction management services or design-build services as described below, may be authorized by NIH when cost, time, and quality benefits will result. In making such determinations, NIH will consider the scope of the project, estimated cost, and other factors deemed relevant.

If a construction management firm is currently employed, the grantee may authorize that firm to perform the construction work. Such authorization requires NIH prior approval and the price for the work involved must not exceed the GMP also approved by NIH.

### 10.3.1 Guaranteed Maximum Price

Under this procedure:

- The Guaranteed Maximum Price (GMP) contracting method can be used in either Construction Manager at Risk contracts or as part of Design-Build Services contracts. In either case, the project must be completed at or below the GMP.

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

- The GMP must be completely itemized, by trade, to include a separation of labor and materials, all markups, and no contingency other than that which will cover change orders as approved by the grantee.

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- After approval of the GMP, all GMP subcontracts must be competed, and there must be at least three bidders to allow for an award.
    - Issue a "sources sought" announcement describing the nature of the construction work required, the separate contracts to be awarded, and the standards for prequalification. It must also describe the complete scope of work with sufficient specificity to ensure response from all interested sources.
    - Pre-qualify all firms that respond to the announcement who are determined by the grantee to meet the prequalification standards.
    - Establish bidder's lists for each of the invitations to bid. The lists must include all firms qualified on the basis of responses to the "sources sought" announcement and may also include other qualified firms known to the grantee.
    - By written invitation, solicit bids from all firms on the bidders list.
    - Consider bids from any contractor who requests permission to bid and who is determined by the grantee to meet the prequalification standards.
    - If three bids cannot be obtained, the grantee must submit, in writing, to the GMO a detailed explanation of why the GMP contractor is unable to comply, along with supporting documentation for NIH consideration and approval of another alternate contracting method.
    - Funds unexpended, due to lower construction costs than estimated in the GMP, must be refunded or credited to the grantee by the contractor and by the grantee to NIH. All costs in excess of the GMP are the responsibility of the GMP contractor.
    - All subcontract prices must be approved by the GMO before making individual awards. The awards shall be made to the lowest-priced responsible, responsive bidders.

### 10.3.2 Construction Manager as Agent

Use of construction management services, under which the grantee contracts for technical consultation during the design stage of a project and for organization and general project oversight of construction activities during the construction phase, is considered professional services and, therefore, may be procured on a negotiated basis rather than by formal advertising. However, the services of CMs may be procured by formal advertising in those cases where State or local governments prohibit the award of construction management contracts on a negotiated basis. Where bids are invited, the bidders should be pre-qualified. Under this procedure, the CM, operating as a member of a grantee-architect-CM team, is responsible for cost estimates during the design and construction as well as cost control, review of design(s) with a view toward value engineering, consultation on construction techniques, construction coordination and scheduling, and oversight of all construction activities. The CM's fee is considered an eligible cost for the purpose of determining the total eligible cost of the project.

### 10.3.3 Construction Manager-at-Risk

A CM-at-Risk is considered a sole proprietorship, partnership, corporation, or other legal entity that assumes the financial risk for construction, rehabilitation, alteration, or repair of a facility at a GMP. The CM-at-Risk serves as a general contractor and provides consultation to the client during the design of the facility and through construction. The terms of the CM's employment must be such as to preclude any conflict of interest. The grantee may authorize the CM as Agent to become the CM-at-Risk to perform the construction services when authorized by NIH.

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Under this procedure:

- The construction management contract must place total financial responsibility on the CM to complete construction of the project at or below a GMP. The CM is required to provide 100 percent performance and payment bonds to ensure that the facility can be completed with the amount of funds available.

- The GMP must be obtained from the CM before NIH will authorize the award of the first construction contract. This requirement applies whether or not phased construction techniques are employed. Each portion of the work for which a separate contract is expected shall be separately priced as an individual line item in the GMP contract.

### 10.3.4 Design-Build Services

In design-build contracting, construction firms respond to a request for proposals by submitting building designs that meet the grantee's performance requirements within a GMP covering all architectural, engineering, and construction services required. The design-build firm must be selected in a manner that will allow maximum feasible competition. Because of the nature of design-build contracting, the following departures from formal advertising are authorized:

- Cost will be treated as a competitive factor although the grantee may insert in the request for proposals a specified maximum permissible figure.

- A contract may be awarded regardless of the number of proposals received or the number of firms determined to have met qualification standards.

- The grantee may negotiate cost or design with one or any number of firms.

The selection of a design-build firm must be accomplished by a process that includes the following activities:

- Preparation of a RFP describing the grantee's design requirements, cost requirements, standards for qualifying firms, and the criteria on which proposals will be judged.

- Public announcement of the RFP.

- Consideration of all proposals from firms that are determined to be qualified.

- Selection of that firm that, in the grantee's judgment, represents the best offer considering both the firm's qualifications and satisfaction of the criteria in the RFP.

On all design-build projects, the 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.

- Justify cost on the basis of comparability with similar construction.

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# 10.4 DESIGN DOCUMENTATION REQUIREMENTS

Unless otherwise specified in the NoA, following award acceptance for construction or modernization grants or award of funds for a major A&R project, the grantee may begin the design phase of the award, which includes the review, and approval of the design documents with the IC program or other designated NIH staff. Funds for construction, modernization, or major A&R will not be released until the final architectural drawings, specifications, construction schedule, and updated cost estimates are reviewed and approved by the NIH IC unless otherwise indicated in the NoA. The release of funds is accomplished by a revised NoA. The purpose of the NIH design review is to ensure that applicable design standards, including, as applicable, the minimum requirements contained in 42 CFR part 52b.12 (see Minimum Requirements for Construction, Modernization, and Major A&R below), have been incorporated into the working drawings and specifications to ensure that program requirements are met, and that the facility will suitably accommodate the activities for which it is planned to be used.

Advertisement for bids may be initiated only after approval of the final construction documents by the NIH awarding IC. The procurement methods to be employed, including any plans that involve a construction management contract with a GMP clause, must be reviewed and approved by the NIH awarding IC.

## 10.4.1 Minimum Design Requirements for Construction, Modernization and Major A&R

The minimum design requirements for NIH grant-supported construction or modernization are set forth in 42 CFR part 52b.12. The *NIH Design Requirements Manual* incorporates the regulatory standards for construction or modernization grants and those for major A&R projects. The *NIH Design Requirements Manual* is available at http://orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/DesignRequirementsManualPDF.htm.

Specific requirements for construction grants are contained in Appendix A, "References, Design and Safety Guidelines, Health and Safety Regulations, Codes and Standards," of the *NIH Design Requirements Manual*. The grantee will be subject to the standards in effect at the time of design or construction (modernization or A&R), as appropriate. Working drawings and specifications submitted for NIH approval (see Design Documentation Requirements above) must conform to the minimum standards in the *NIH Design Requirements Manual*. The *NIH Design Requirements Manual* also include policies, design standards, and technical criteria for use in planning, designing, and constructing or altering/renovating buildings owned or leased for use by NIH. Grantees are not subject to the NIH site specific requirements contained in the *NIH Design Requirements Manual* but should meet the intended design objectives in such cases.

Grantees also must ensure that each project meets the requirements of the applicable State and local codes and ordinances. Where State or local codes are proposed as a basis for facility design in lieu of the NIH design requirements, a prior determination must be made by the NIH awarding IC that the specific State or local code is equivalent to, or exceeds, NIH requirements. If State and local codes or requirements exceed the design requirements set forth in NIH regulations, the *NIH Design Requirements Manual* or program guidelines, the more stringent requirements will apply.

In planning and designing construction or modernization projects, recipients must consider that the facility is generally subject to an extended usage requirement, e.g., 10 or 20 years, after the date of occupancy and it should be constructed accordingly.

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NIH will monitor compliance with design requirements during the project's design and construction phase. Grantees (or applicants) with questions concerning the applicability of requirements contained in the *NIH Design Requirements Manual* should consult with the NIH PO.

# 10.5 EQUAL EMPLOYMENT OPPORTUNITY AND LABOR STANDARDS

Labor standards and equal employment opportunity requirements for federally assisted construction must be specified in the information provided to potential bidders/offerors on contracts for construction services under NIH construction and modernization grants and major A&R projects and must be included in the resulting contract documents (see 45 CFR part 74, Appendix A, and 45 CFR part 92.36(i)). NIH construction and modernization grants and major A&R projects (and contracts under them) are not subject to the requirements of the Davis-Bacon Act, unless the authorizing statute for the program/award specifically requires compliance.

## 10.5.1 Equal Employment Opportunity

Contracts (and subcontracts) for construction (including modernization or major A&R) are subject to the requirements of EO 11246 (September 24, 1965), as amended and implemented in 41 CFR part 60-1 by OFCCP, DoL. The grantee is required to include the "Equal Opportunity Clause" at 41 CFR part 60-1.4(b) in any contract for construction services under the grant. The contractor must be directed to include this clause in any applicable subcontracts.

In addition, grantees and contractors providing construction services under NIH grants are required to comply with the solicitation and contract requirements for affirmative action specified in 41 CFR part 60-4 for contracts in specified geographical areas that will exceed $10,000. These requirements are specified in the "Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity" and the "Standard Federal Equal Employment Opportunity Construction Contract Specifications" subsections of 41 CFR part 60-4.

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

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

## 10.5.2 Nonsegregated Facilities

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

- Does not, and will not, maintain any facilities it provides for its employees in a manner that is segregated on the basis of race, color, religion, sex or national origin;
- Does not, and will not, permit its employees to perform their services at any location, under the contractor's control, where segregated facilities are maintained; and
- Will ensure that prospective subcontractors under any covered subcontract do not maintain segregated facilities or perform services at segregated facilities.

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## 10.5.3 Labor Standards

### 10.5.3.1 Contract Work Hours and Safety Standards

Contractors and subcontractors providing construction services under NIH construction or modernization grants or major A&R projects with contracts or subcontracts exceeding $100,000 are subject to the requirements of the Contract Work Hours and Safety Standards Act, 40 U.S.C. 3701, et seq., concerning the payment of overtime and the maintenance of healthful and safe working conditions.

Wages paid any laborer or mechanic employed by the contractor or subcontractor must be computed on the basis of a standard workweek of 40 hours. For all work in excess of the standard workweek, mechanics and laborers shall be compensated at a rate not less than one-and-a-half times the basic rate of pay. If this requirement is violated, the contractor or subcontractor is liable to the employee for the unpaid wages and may be liable to the Federal government for liquidated damages. NIH or the 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.

### 10.5.3.2 Disposition of Unclaimed Wages

During or after the period of performance of a contract for construction services under an NIH grant, if it is discovered that an employee is entitled to wages but cannot be located for the purposes of payment (or for some reason refuses to accept payment), the 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, modernization, or major A&R project was 100 percent funded by NIH, or an amount representing the percentage of NIH participation in the project. If the project was funded by more than one NIH or HHS program at differing rates, the refund should be based on an average percentage calculated by weighting each program's rate of participation by the dollar amount of that program's contribution.

If the contractor has made a reasonable effort to locate the employee by having mail forwarded and contacting the employee's union, the 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.

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# 10.6 REAL PROPERTY MANAGEMENT STANDARDS

## 10.6.1 General

Unless alternate requirements are specified in the governing statute:

- Construction, modernization and major A&R under research grants are subject to the requirements of 42 CFR part 52b.
- Major A&R under center grants or minor A&R under other types of grants/mechanisms is subject to the provisions of 45 CFR parts 74.30 through 74.32 and 74.37 or 92.31, as applicable, regarding use, transfer of title, and disposition.

Statutory provisions may specify alternate requirements for the length of the grantee's accountability obligations, the Federal right of recovery, or waivers. To the extent statutory provisions differ from the requirements of 42 CFR part 52b and/or 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, modernized, or otherwise altered as part of a major alteration with NIH grant support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the 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, the mortgagee (grantee) must pay NIH an amount equal to the share of the sales proceeds otherwise due the recipient (mortgagor) times the Federal share in the property.

Any NIH assignment of the property and mortgage responsibilities to any party other than NIH shall be subject to prior approval of the mortgagor.

## 10.6.2 Notice of Federal Interest

To protect the Federal interest in real property constructed, or where applicable, improved with NIH grant funds, grantees shall record a NFI in the appropriate official records of the jurisdiction in which the property is located as required by 45 CFR part 74.37 and the NIHGPS. The NFI is required when use and disposition conditions apply to the property as stated in the NoA. The time of recordation shall be when construction begins. The grantee should consult with the GMO prior to recording the NFI, if necessary, to determine if the NFI is required under the award. Fees charged for recording the NFI may be charged to the grant (see Allowable and Unallowable Costs and Activities in this chapter). A copy of the recorded NFI must be provided to the GMO within 10 days following the date of recordation. To obtain a sample NFI, contact the GMO.

## 10.6.3 Insurance Requirements

Builder's risk insurance is required at the time construction begins. The insurance must cover potential losses after initiation, but before completion, of the construction or modernization caused by theft, fire, vandalism, and other types of accidental loss or damage to the structure.

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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 a facility constructed with NIH grant support, or portion of a facility modernized or modified under a major A&R project, (that conforms to the design and specifications approved by the NIH and is available for occupancy) over to the grantee (i.e., the date of the final acceptance of the building or portion of a building) or the date of beneficial occupancy, whichever comes first.

If title to real property constructed, modernized, or altered under a major A&R project under an NIH grant vests (or will vest upon completion) in the 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 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 IC, such as legal or title opinion, that it has good and merchantable title free of all mortgages or other foreclosable liens to all land, rights of way, and easements necessary for the project. In instances where a 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 (i.e., 5 years or more), 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 (whether owned or leased by the grantee) from risk of partial and total physical destruction. When the Federal participation covers only a portion of a building, the insurance should cover the total cost of the facility, because any damage to the building could make the building unusable and could thus affect the Federal interest. The insurance policy is to be maintained for the duration of the Federal interest in the property (see Real Property Management Standards—Use of Facility and Disposition in this chapter). The cost of insurance coverage after the period of grant support must be borne by a source other than the grant that provided the funds for the grant-supported project. The grant account will not remain active for this purpose.

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

The NIH awarding IC 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 assurance should state the source of the funds, such as the organization's endowment or other special funds set aside specifically for this purpose.

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### 10.6.4 Use of Facility and Disposition

NIH construction grants require that the facility be used for biomedical or behavioral research for as long as needed for that purpose for the period prescribed in the NoA. The date of beneficial occupancy is the date that a facility constructed or modernized with NIH grant support conforming to the design and specifications approved by the NIH are available for occupancy and fully operational to carry out all intended facility/research activities. During that time, the grantee must use the facility for the originally authorized purpose unless it obtains prior approval from the NIH awarding IC to use the facility for an alternate purpose. To ensure a grantee's compliance with the facility usage requirement, the IC GMO will periodically (e.g., at least every two years) survey the recipient throughout the usage period and request a self-certification concerning continued use. NIH may also obtain the names of the investigator(s) occupying the space and an indication of their research interests. Most of the monitoring will be accomplished in this manner. However, NIH staff may perform periodic site visits to observe the use of the grant-supported space throughout the usage period. After the required usage period, NIH will no longer directly monitor the use of the space.

When use and disposition conditions apply to real property supported under an NIH award, the grantee may not convey, transfer, assign, mortgage, lease, or in any other manner encumber such property without the prior written approval from the awarding office. If the grantee decides that the grant-support space is no longer needed before the expiration of the period of Federal interest, the grantee must request written disposition instruction from the awarding office. This action must be done prior to the grantee's making any irreversible commitment related to property disposition. In this case, NIH may consider an alternate use of the facility or provide disposition instructions.

In determining whether to approve an alternate use of the facility, NIH will take into consideration the extent to which the facility will be used for:

- Other health-related purposes consistent with the authorizing legislation of the program.
- Other health-related activities that are consistent with the mission of the IC; or
- Training and instruction in health fields for health professionals or health-related information programs for the public.

The usage obligation may also be transferred to another facility with the prior approval of NIH. If approved, the remaining usage obligation shall be released from the original facility constructed with grant funds and transferred to the new facility. The grantee remains subject to all other requirements imposed by the NoA or successor document (if the change occurs following the period of grant support).

For disposition of property acquired on an amortized acquisition basis, the computation of the Federal share of real property acquired with long-term debt financing will be computed for each year of grant support in which Federal funds are used to meet all or a portion of the down payment and/or principal on the mortgage.

### 10.6.5 Real Estate Appraisals

If a real estate transaction funded in whole or in part by NIH requires the use of a real estate appraisal (including, but not limited, to appraisals to determine the Federal share of real property and appraisals to determine required insurance levels), the appraisal must be performed by appraisers certified or licensed by the applicable State in accordance with the requirements established by Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (Public Law 101-73).

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# 10.7 ALLOWABLE AND UNALLOWABLE COSTS AND ACTIVITIES

The following lists indicate types of costs and activities generally allowable and unallowable under NIH construction or modernization grants and major A&R projects unless otherwise noted in the FOA. The lists are not all-inclusive. Program guidelines, the NoA, and other terms and conditions of the award should be consulted for the specific costs allowable under a particular program or grant.

Major A&R is unallowable under foreign grants and foreign components in domestic grants.

The allowability and unallowability of costs and activities applies to the use of Federal funds and funds expended by the grantee to satisfy a matching requirement (see Matching Requirement in this chapter).

**Allowable costs and activities include the following:**

- Acquisition and installation of fixed equipment.
- Appraisals
- Architectural and engineering services. Also see Pre-award costs below.
- Bid advertising
- Bid guarantees and performance and payment bonds. Bid guarantees and performance and payment bonds are allowable as provided in 45 CFR part 74.48 or 92.36(h). A bid guarantee is a form of security assuring that the bidder will not withdraw a bid within the period specified for acceptance and will execute a written contract and furnish required bonds. Performance bonds secure fulfillment of all the contractor's obligations under the contract and payment bonds assure payment as required by law to all persons supplying labor and material in the execution of the work provided for in the contract.
- Contingency fund. To provide for unanticipated costs, applicants for construction grants may include a project contingency amount with the initial total allowable cost estimates. Contingency funds will be limited to 15 percent of the total allowable costs before bids are received and must be reduced to 10 percent after a construction contract has been awarded. NIH may maintain control up to 3% of the total contingency for unanticipated program specific changes during the course of the project.
- Filing fees for recording the NFI. See Real Property Management Standards—Notice of Federal Interest in this chapter.
- Force Account Labor. If the grantee's own construction and maintenance staffs are used in carrying out construction or modernization activities (i.e., force account), the associated costs are allowable provided the grantee can document that a force account is less expensive than if the project were competitively bid and can substantiate all costs with appropriate receipts for the purchase of materials and certified pay records for the labor involved. This requires prior approval by the NIH awarding IC.
- General conditions (e.g. moveable site trailers, port-a-johns, hard hats, temporary or limited duration signage, security costs during construction).

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- Inspection and commissioning fees.

- Insurance. Costs of builders risk insurance, title insurance, physical destruction insurance, and liability insurance are generally allowable. Physical destruction, and liability insurance usually are treated as F&A costs but may be treated as direct costs in accordance with the established policy of the grantee, consistently applied regardless of the source of funds. Builder's risk insurance and title insurance may be charged to the grant in proportion to the amount of NIH participation in the property (see Real Property Management Standards—Insurance Requirements in this chapter).

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

- Pre-award costs. Costs incurred before award for architect's fees, consultant's fees and environmental analysis necessary to the planning and design of the project are allowable if the project is subsequently approved and funded. Pre-award construction or modernization costs are generally unallowable unless NIH grants an exception.

- Profit/fee for contractors/subcontractors. Allowable as part of the overall cost/price of a contract consistent with commercial practice.

- Project management.

- Relocation expenses related to the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (49 CFR part 24).

- Sidewalks necessary for use of facility.

- Site survey and soil investigation.

- Site clearance. Site clearance costs are allowable as long as they are reflected in the bid.

- Threat-risk assessment. Costs incurred for a site-specific or project-specific assessment of security risk by a qualified professional are allowable.

- NEPA and historic preservation analysis. Costs associated with evaluation of the environmental effects and historic preservation effects of proposed construction, modernization, or A&R activity and obtaining public input, producing the necessary studies, analysis, and resultant reports are allowable. Also see Pre-award costs above.

**Unallowable costs and activities include the following:**

- Bonus payments to contractors. Bonus payments other than earned incentive payments to contractors under formal incentive arrangements are unallowable. An incentive arrangement is used to motivate contractors to provide required supplies or services at lower costs and, in certain instances, with improved delivery or technical performance, by relating the amount of profit or fee payable under the contract to the contractor's performance.

- Construction of shell space designed for completion at a future date.

- Consultant fees not related to actual construction.

- Damage judgment suits.

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- Equipment purchased through a conditional sales contract. A conditional sale is a type of agreement to sell under which the seller retains title to goods sold and delivered to a purchaser until full payment has been made.
- F&A costs.
- Fund-raising expenses.
- Interior and exterior decorating fees (e.g. purchase of artwork, sculpture, etc).
- Land acquisition.
- Landscaping and irrigation costs.
- Legal services not related to title certification.
- Movable equipment.
- Off-site improvements. Off-site improvements, such as parking lots, are not allowable.

# 10.8 ADMINISTRATIVE REQUIREMENTS

## 10.8.1 Prior Approval Requirements

Grantees must obtain written prior approval from the GMO for the following types of recipient-initiated project or budget changes:

- Any applicable change as specified in Administrative Requirements—Changes in Project and Budget in IIA.
- Revision that would result in a change in scope of the project, change in project site and/or location, including proposed modifications that would materially alter the costs of the project, space utilization, or financial outlay (including Federal/non-Federal cost share adjustments), resulting in changes in the previously approved procurement method or contract. Modifications that would materially alter the costs include the transfer of funds between construction and non-construction work.
- Deviations from design requirements.
- Alternate contracting methods.
- Revision that would increase the amount of Federal funds needed to complete the project.
- Extension of the project period with or without funds.
- Change in the use of the facility (see Real Property Standards—Use of Facility and Disposition in this chapter).
- Transfer of the remaining usage obligation to another facility.

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The request for approval must include sufficient information to allow NIH review of the circumstance(s) and need for the proposed change. For changes affecting construction contracts, if the grantee receives written prior approval from the GMO, the grantee may make or authorize the approved modifications to the construction contract. Minor modifications to construction contracts may be made without NIH awarding IC prior approval. However, copies of all change orders to construction contracts must be retained as grant-related records (see Administrative Requirements—Monitoring—Record Retention and Access in IIA).

### 10.8.2 Alteration and Renovation Projects Under Non-construction Grants

Two copies of each of the following documents must be submitted with each request for approval of minor A&R 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

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- 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 chapter for construction grants.

## 10.9 CLOSEOUT

Immediately upon completion of construction, modernization, or alteration under a major A&R project the grantee should contact the awarding IC GMO. Under construction grants, the grantee will generally be required to submit the following documents within 90 days following the completion of the project as part of the closeout process:

- A final tabulation of net assignable space supported under the award for each program activity.
- The actual cost of construction per gross and net square foot/meter.
- The actual total allowable project costs after construction per gross and net square foot/meter.
- Actual date of beneficial occupancy of the facility.
- A simplified floor plan or space assignment drawing in electronic format clearly marked to identify the grant-supported space.
- Final record as-built construction documents.
- Electronic submission of the FSR reflecting both the Federal and non-Federal share of outlays when matching is required.
- A written assurance signed by the AOR stating that the grantee has the required insurance coverage and agrees to maintain the required insurance for the applicable duration of the Federal interest in the property or an indication that the grantee is self-insured against the risks involved and the source of funds.

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## 10.10 PUBLIC POLICY REQUIREMENTS

In addition to the public policy requirements and objectives specified in IIA, grants for construction, modernization or major A&R projects are subject to the public policy requirements in this section. These requirements may be specified by statute, regulation, executive order, or policy, and apply regardless of the type of grantee. Exhibit 11 may be used as guidance; however, some of the requirements for construction or modernization grants or major A&R activities may not be applicable to your project or program. Specific questions about whether a particular requirement applies should be directed to the GMO of the awarding IC. Recipients of construction or modernization grants and funding for major A&R projects also must require contractors and subcontractors providing construction services to comply with certain Federal labor standards. These labor standards are discussed in Equal Employment Opportunity and Labor Standards in this chapter. Following are highlights of public policy requirements:

- ***Architectural Barriers Act of 1968, as amended (42 U.S.C. §§ 4151 et seq.).*** The Architectural Barriers Act of 1968, as amended, the Federal Property Management Regulations 101-19.6

(41 CFR part 101-19.6), and the Uniform Federal Accessibility Standards issued by the General Services Administration (41 CFR part 101-19.6, Appendix A) set forth requirements to make facilities accessible to, and usable by, the physically handicapped and include minimum design standards. All new facilities constructed with NIH grant support must comply with these requirements. These minimum standards must be included in the specifications for any NIH-funded new construction unless the 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.

- ***Clean Air Act (42 U.S.C. 7401 et seq.), and Federal Water Pollution Control Act (Clean Water Act), as amended (33 U.S.C. 1251 et seq.).*** Provide for the protection and enhancement of the quality of the nation's air resources to promote public health and welfare, and for restoring and maintaining the chemical, physical and biological integrity of the nation's waters; for contracts exceeding $100,000.

- ***Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.).*** Assurance of project consistency with the approved State management program developed under the Act.

- ***Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874).*** When required by statute.

- ***Davis-Bacon Act (40 U.S.C. §§276a to 276a-7).*** When required by statute.

- ***Earthquake Hazards Reduction Act of 1977, as amended (Public Law 95-124), and EO 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990).*** Apply to NIH-assisted construction located in the applicable geographic location. The EO requires that new federally assisted or regulated buildings be designed and constructed using appropriate seismic standards compliant with State, country, or local jurisdictional building ordinances. Where necessary, special structural and other features to protect life and minimize damage to facilities from tornadoes also may be required.

- ***Endangered Species Act of 1973, as amended (P.L. 93-205).*** For the protection of endangered species.

- ***Flood Disaster Protection Act of 1973 - Flood Insurance - The Flood Disaster Protection Act of 1973, as amended (Public Law 93-234).*** Provides that no Federal financial assistance to acquire, modernize, or construct property may be provided in identified flood-prone communities in the United States, unless the community participates in the National Flood Insurance Program and flood insurance is purchased within 1 year of the identification. Lists of flood-prone areas that are eligible for flood insurance are published in the *Federal Register* by FEMA.

- ***Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.).*** Prohibits the use of lead-based paint in construction or rehabilitation of residence structures.

- ***National Environmental Policy Act of 1969 - NEPA, as amended (Public Law 91-190).*** Establishes national policy goals and procedures to protect and enhance the environment, including protection against natural disasters. NEPA requires all Federal agencies to consider the reasonably foreseeable environmental consequences of any major Federal activity, including grant-supported activities. If NIH determines that NEPA applies to grant-supported activities, NIH

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will require that the environmental aspects of the activity be reviewed and evaluated by NIH technical staff before final action on the application. This determination also includes determinations concerning floodplain management pursuant to EO 11988, Floodplain Management (May 24, 1977) (42 FR 26951, 3 CFR, 1977 Comp., p. 117) and EO 11990, Protection of Wetlands (May 24, 1977) (42 FR 26961, 3 CFR, 1977 Comp., p. 121).

Because projects for construction, modernization, or major A&R activities have the potential to affect the environment, NIH requires that applicants for this type of support provide information on anticipated environmental impact as part of their applications. Applicants may use the Review of Environmental and Other Impacts document that is available at http://www.ncrr.nih.gov/research%5Finfrastructure/environmental_analysis_form.doc as part of the application package to supply this information. An alternate format can be used as long as equivalent environmental and other impacts information accompanies the application.

The NIH will review the Environmental and Other Impacts information contained in the application to assess the level of environmental impact of the proposed project. It is the responsibility of NIH to determine which of the following will apply to the proposed project:

- ***Environmental Impact Statement (EIS).*** A document required of federal agencies by the NEPA for major projects or legislative proposals significantly affecting the environment. A tool for decision making, it describes the positive and negative effects of the undertaking and considers alternatives.

- ***Environmental Assessment (EA).*** An environmental analysis prepared pursuant to the NEPA to determine whether a federal action would significantly affect the environment and thus require a more detailed environmental impact statement.

- No Further Action is Required.

If NIH determines that an EA or an EIS is required, the applicant (recipient) must conduct the appropriate environmental review and provide the necessary documentation to NIH for review, approval, and processing. NIH will provide advice and assistance to the applicant (recipient), as necessary, concerning review procedures; evaluate the results of the review; and make the final decision on environmental impact as required by NEPA.

Applicants also must (1) provide a current listing and copies, as applicable, of all relevant licenses, permits, and/or other approvals required including, but not limited to, the State and local air, water quality, and zoning board reports, and (2) indicate the State, local, and regional planning authorities contacted or consulted regarding the application and briefly discuss the proposed facility with respect to regional development plans.

Applicants are not required to incur costs for extensive consultant services at the application stage; therefore, hiring of consultants to develop detailed data and elaborate presentations is discouraged and such costs generally will not be allowable as pre-award costs.

- ***Public Disclosure – Section 102 of NEPA and EO 11514.*** Section 102 of NEPA and EO 11514 (March 5, 1970) provide for public comment and participation in the environmental impact review process. When there is an environmental impact (in accord with NEPA), the applicant must publicly disclose the project in a newspaper or other publicly available medium and to describe any environmental impacts that affect the protection and enhancement of environmental quality concurrent with notification to the SPOC (see Public Policy Requirements—Executive

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Orders—Intergovernmental Review of Programs under Executive Order 12372 in this chapter). An example of a sample disclosure statement follows:

"Notice is hereby given that the Uptown Medical School proposes to construct additional space, partially utilizing Federal funds. The proposed construction project is the addition of 251 net square meters connected to the existing Allen Building, which is located at 5333 Main Street, Downtown, Ohio.

The Medical School has evaluated the environmental and community impact of the proposed construction. There will be (*appropriate text will describe impact*). The Medical School anticipates that no significant permanent environmental impacts are foreseen, however, this determination is ultimately the responsibility of the awarding Federal agency. In accordance with Executive Order 11514 (March 5, 1970), which implements the National Environmental Policy Act of 1969, as amended, any individual or group may comment on, or request information concerning, the environmental implications of the proposed project. Communications should be addressed to the Office of Planning, Uptown Medical School, and must be received by (date). The Federal grant application may be reviewed at the Office of the Dean, School of Medicine, 5333 Main Street, during normal working hours."

- ***National Historic Preservation Act of 1966 and Archaeological and Historic Preservation Act of 1974.*** Under the provisions of the National Historic Preservation Act, as amended (16 U.S.C. 470 et seq.), and the Archaeological and Historic Preservation Act of 1974, as amended (16 U.S.C. 469a-1 et seq.), the Secretary of the Interior has compiled a National Register of Historic Places—sites and buildings of significant importance to U.S. history. These statutes require that, before approval of a grant related activity, NIH take into account the effect on these sites of the proposed activity. NIH is primarily responsible for determining whether activities will affect a property listed in the National Register or one that meets the eligibility criteria for inclusion, even if not included in the National Register at the time the application is submitted. The National Register of Historic Places may be obtained from the State Liaison Officers designated by their respective states to administer this program or from the Advisory Council on Historic Preservation, http://www.achp.gov/. The National Trust for Historic Preservation is at http://www.nationaltrust.org/.

  If an eligible or potentially eligible historic property will be affected, the applicant must obtain clearance from both the appropriate State Historic Preservation Office and Tribal Historic Preservation Office before submitting the application. Failure to obtain this clearance will delay NIH action on an application. The State Historic Preservation Liaison Officer or the National Trust for Historic Preservation may be contacted for additional details. Information on Tribal Preservation Officers and Offices is available at http://www.achp.gov/thpo.html.

- ***Rehabilitation Act of 1973.*** The HHS implementation of section 504 of the Rehabilitation Act of 1973 is found in 45 CFR part 84, Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance. Section 504 is designed to eliminate discrimination on the basis of handicap in any program or activity receiving Federal financial assistance. Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such manner that the facility or part of the facility is readily accessible to and usable by handicapped persons. Furthermore, each facility or part of a facility which is modernized or altered by, on behalf of, or for the use of a recipient in a manner that affects or could affect the usability of the facility or part of the facility shall, to the maximum extent feasible, be modernized or altered in such manner that the altered portion of the facility is readily accessible to and usable by handicapped persons. Design, construction, or alteration of

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buildings shall conform to the Federal Property Management Regulations at 41 CFR part 102 subchapter C, Real Property, Part 102-76.

- ***Safe Drinking Water Act (Title XIV of the Public Health Service Act, as amended).*** For the protection of underground sources of drinking water.

- ***Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Uniform Relocation Act).*** HHS requirements for complying with the Uniform Relocation Act are set forth in 49 CFR part 24. Uniform relocation assistance and real property acquisition for Federal and federally assisted programs. The Uniform Relocation Act, 42 U.S.C. 4601 et seq., applies to all programs or projects undertaken by Federal agencies or with Federal financial assistance that cause the displacement of any person. The HHS requirements for complying with the Uniform Relocation Act are set forth in 45 CFR part 15, which references 49 CFR part 24. Those regulations provide policies and procedures for the acquisition of real property, including acquisition by 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.

- ***Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.).*** Related to protecting components or potential components of the national wild and scenic rivers system.

## 10.10.1 Executive Orders

- ***Intergovernmental Review of Federal Programs (July 14, 1982), as amended, under Executive Order 12372.*** EO 12372 requires consultation with State and local officials on certain proposed Federal assistance. For HHS, these requirements are implemented in 45 CFR part 100, Intergovernmental Review of Department of Health and Human Services Programs and Activities. NIH construction and modernization grants are subject to these requirements. Applicants from states that have chosen to participate in the intergovernmental review process should contact their SPOC as early as possible to alert the SPOC to the planned application and to obtain necessary instruction on the State process (see http://www.whitehouse.gov/omb/grants_spoc for a list of SPOCs). Indian tribal governments are not subject to these requirements.

  SPOCs are given 60 days to review applications. To accommodate this time frame and the NIH review process, an applicant must provide a copy of the application to the SPOC no later than the time the application is submitted to NIH. SPOC comments must be submitted to NIH with the application, or the application must indicate the date on which the application was provided to the SPOC for review. If SPOC comments are not submitted with the application, the applicant must provide them upon receipt and may include its reaction to the comments, or it must notify NIH that it did not receive any SPOC response.

- ***Executive Order 11988, Floodplain Management (May 24, 1977) (42 FR 26951, 3 CFR, 1977 Comp., p. 117).*** Uneconomical, hazardous, or unnecessary use of flood plains for construction.

- ***Executive Order 11990, Protection of Wetlands (May 24, 1977).*** See 42 FR 26961, 3 CFR, 1977 Comp., p. 121.

- ***Executive Order 12185, Conservation of Petroleum and Natural Gas (Dec. 17, 1979).*** See 44 FR 75093, 3 CFR, 1979 Comp., p. 474.

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- ***Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990).*** See 3 CFR, 1990 Comp., p. 269. See Earthquake Hazards Reduction Act bullet in the Construction—Public Policy Requirements section.

- ***Executive Order 12770 – Metric System.*** Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs. All construction, modernization, or A&R (major or minor) supported by NIH grant funds must be designed using the metric system.

**Exhibit 11. Summary of Requirements Applicable to Construction, Modernization, and Major A&R Activities**

**Program Regulation**

| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| NIH Construction Grants Regulations (42 CFR part 52b) | Applicable | Applicable | Applicable to major A&R under a research project grant; does not apply to minor A&R and A&R funded under an NIH Center grant. |

**Public Policy Requirements**

| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| Architectural Barriers Act of 1968 | Applicable | Applicable | Applicable |
| Clean Air and Clean Water Act | Applicable | Applicable | Applicable |
| Coastal Zone Management Act of 1972 | Applicable | Applicable | Applicable |
| Copeland Act | As required by statute | As required by statute | As required by statute |
| Davis-Bacon Act | As required by statute | As required by statute | As required by statute |
| Earthquake Hazards Reduction Act of 1977 | Applicable | N/A | N/A |
| Endangered Species Act of 1973 | Applicable | Applicable | Applicable |
| Flood Disaster Protection Act of 1973 | Applicable | N/A | N/A |
| Lead-Based Paint Poisoning Prevention Act | Applicable | Applicable | Applicable |

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| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| National Environmental Policy Act (NEPA) of 1969 | Applicable | Applicable | As specified by NIH |
| Public Disclosure – Section 102 of NEPA and EO 11514 (as applicable for the protection and enhancement of environmental quality) | Applicable when the projects involves an environmental impact | Applicable when the projects involves an environmental impact | Applicable when the projects involves an environmental impact |
| Rehabilitation Act of 1973 (45 CFR part 84) | Applicable | Applicable | Applicable |
| Safe Drinking Water Act | Applicable | Applicable | Applicable |
| Uniform Relocation Act (49 CFR part 24) | Applicable | N/A | N/A |
| Wild and Scenic Rivers Act of 1968 | Applicable | Applicable | Applicable |

**Executive Orders**

| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| Executive Order 12372, Intergovernmental Review of Federal Programs | Applicable | Specified in the FOA | Applicable |
| Executive Order 11988, Floodplain Management | Applicable | Applicable | Applicable |
| Executive Order 11990, Protection of Wetlands | Applicable | Applicable | Applicable |
| Executive Order 12185, Conservation of Petroleum and Natural Gas | Applicable | Applicable | Applicable |
| Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction | Applicable | N/A | N/A |
| Executive Order 12770, Metric System | Applicable | Applicable | Applicable |

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### Other Requirements

| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| Matching | Specified in the FOA and NoA | Specified in the FOA and NoA | N/A |
| NIH Design Requirements Manual | Applicable | Specified in the FOA | Applicable |
| Design Documentation Requirements | Applicable | Applicable | Applicable |

### Procurement Requirement

| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| Liquidated Damages | Applicable | Applicable | Applicable |

### Equal Employment Opportunity and Labor Standards

| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| Equal Employment Opportunity | Applicable | Applicable | Applicable |
| Nonsegregated Facilities | Contracts exceeding $10,000 | Contracts exceeding $10,000 | Contracts exceeding $10,000 |
| Contract Work Hours and Safety Standards | Contracts exceeding $100,000 | Contracts exceeding $100,000 | Contracts exceeding $100,000 |
| Disposition of Unclaimed Wages | Applicable | Applicable | Applicable |

### Real Property Standards

| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| Real Property Management Standards | Applicable | Applicable | Applicable |
| Notice of Federal Interest | Applicable | Applicable | Applicable |
| Title Insurance | Applicable unless waived | Applicable unless waived | Applicable unless waived |
| Physical Destruction Insurance | Applicable unless waived | Applicable unless waived | Applicable unless waived |

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| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| Use of Facility and Disposition | Specified in the FOA and NoA | Specified in the FOA and NoA or 45 CFR part 74.32(b) or 45 CFR part 92.31 | As specified by NIH in accordance with 45 CFR part 74.32(b) or 45 CFR part 92.31 |

**Closeout**

| Requirement | Type of Activity: Construction Grant | Type of Activity: Modernization Grant | Type of Activity: Major A&R Project |
|---|---|---|---|
| Final Record As-built Construction Documents | Applicable | Applicable | N/A |

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# 11 RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS

## 11.1 GENERAL

This chapter includes general information about Kirschstein-NRSA individual fellowships and institutional research training grants. Separate but all inclusive sections are provided for each; therefore some information may appear duplicative but is provided separately so that nuances between individual fellowships and institutional training grants are covered. Many of the requirements of IIA also apply; this chapter of IIB includes appropriate cross-references to IIA when applicable.

### 11.1.1 Background

Section 487 of the PHS Act (42 U.S.C. 288) provides authority for NIH to award Kirschstein-NRSA individual fellowships to support predoctoral and postdoctoral training of individuals to undertake biomedical, behavioral, or clinical research at domestic and foreign, public and private institutions (profit and non-profit). Section 487(a)(1)(B) authorizes Kirschstein-NRSA institutional research training grants and limits institutional Kirschstein-NRSA support to training and research at domestic public and 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 training, health-related teaching, or any combination of these activities. (See Payback Requirements in this chapter.) The regulations at 42 CFR part 66 apply to these awards.

### 11.1.2 Nondiscrimination

The Kirschstein-NRSA program is conducted in compliance with applicable laws that provide that no person shall, on the grounds of race, color, national origin, handicap, or age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity (or, on the basis of sex, with respect to any education program or activity) receiving Federal assistance. Applicant organizations are required to have appropriate Assurance of Compliance forms filed with HHS's OCR before a grant may be made to that institution. The NIH awarding IC should be contacted if there are any questions concerning compliance. (See Public Policy Requirements and Objectives—Civil Rights in IIA for detailed requirements.)

## 11.2 INDIVIDUAL FELLOWSHIPS

### 11.2.1 General

The Kirschstein-NRSA program helps ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Fellowship activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH mission. Under this authority, NIH awards individual postdoctoral fellowships (F32) to promising applicants with the potential to become productive, independent investigators in fields related to the mission of the NIH ICs. 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; specific FOAs should be consulted for guidance.

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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.

## 11.2.2 Eligibility

### 11.2.2.1 Research Areas

Kirschstein-NRSA fellowships may be made for research training in areas that fall within the missions of the NIH ICs. Applications that do not address these areas will be returned. An increased emphasis has been placed on the research training of physicians. The HHS Secretary is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of 2 consecutive years of biomedical, behavioral, or clinical research training. NIH recognizes the critical importance of training clinicians to become researchers and encourages them to apply. For those who have a doctoral-level health professional degree, the proposed training may be used to satisfy a portion of the degree requirements for a master's degree, a doctoral degree, or any other advanced research degree program.

### 11.2.2.2 Research Training Program

The Kirschstein-NRSA fellowship must be used to support a program of research training. It may not support studies leading to M.D., D.O., D.D.S., D.V.M., or other similar clinical, health professional degrees except when those studies are part of a formal combined research degree program such as the M.D./Ph.D. Similarly Kirschstein-NRSA fellowships may not support the clinical portion of residency training. Research fellows in clinical areas are expected to devote full time effort to the proposed research training and to confine clinical duties to those that are part of the research training.

### 11.2.2.3 Degree Requirements

***Predoctoral Training.*** Individuals must have received, as of the activation date of their Kirschstein-NRSA pre-doctoral fellowship award, a baccalaureate degree 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.D.S, D.M.D., D.C., D.O., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.Sc., D.P.T., Pharm.D., N.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign institution. Also acceptable is a statement by an AOR of the degree-granting institution that all degree requirements have been met. It is the responsibility of the sponsoring institution, not the NIH, to determine if a foreign degree is equivalent.

***Senior Fellows.*** As of the beginning date of their award, senior fellows must have a doctoral degree (as specified in Postdoctoral training referenced above) and at least 7 subsequent years of relevant research and professional experience. The senior fellowship is awarded to provide opportunities for experienced scientists to make major changes in the direction of their research careers or to broaden their scientific backgrounds by acquiring new research capabilities. In addition, these awards will enable individuals who are beyond the new investigator stage to take time from regular professional responsibilities to enhance their capabilities to engage in health-related research. Senior fellowships are made for full-time research training. 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

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Senior Fellows (F33) program announcement available on the NIH Web site at http://grants.nih.gov/training/nrsa.htm - fellowships.

### 11.2.2.4 Citizenship

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence by the time of award. Noncitizen nationals are individuals, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on 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 fellowship applicant selected to receive an award must provide a notarized statement of admission for permanent residence prior to award.

Fellowship applicants who have been lawfully admitted for permanent residence, i.e., have a Permanent Resident Card or other legal verification of such status, should check the Permanent Resident box in the citizenship section on the PHS Fellowship Supplemental Form of the fellowship application. Fellowship applicants who have applied for and have not yet been granted admission as a permanent resident should check the box indicating Permanent Resident of U.S. Pending.

Individuals with a Conditional Permanent Residency Status may still apply for individual fellowships. However, in all cases when permanent residency status is involved, it is the responsibility of the sponsoring institution to assure the individual remains eligible for NRSA support for the period of time of any award.

When an application involving Permanent Residency is selected to receive an award, prior to any award being issued, a notarized statement will be required that documents that a licensed notary has seen the individual's valid Permanent Resident Card or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S.

Individuals on temporary or student visas are not eligible to apply for Kirschstein-NRSA individual fellowships unless they have begun the process for becoming a permanent resident and expect to be admitted as a permanent resident by the earliest possible award date.

### 11.2.2.5 Sponsorship

***General.*** Before submitting a Kirschstein-NRSA individual fellowship application, the fellowship applicant must identify a sponsoring institution and an individual who will serve as a sponsor (also called mentor or supervisor) and supervise the training and research experience. The sponsoring institution may be domestic or foreign, public or private (for-profit or non-profit), including the NIH intramural programs, other Federal laboratories, and units of State and local governments. The sponsoring institution is legally responsible for providing facilities for the applicant and financially responsible for the use and disposition of any funds awarded based on the application. The sponsor should be an active investigator in the area of the proposed research who will directly supervise the fellow's research. The sponsor must

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document in the application the training plan for the applicant as well as the availability of staff, research support, and facilities for high-quality research training. In most cases, postdoctoral fellowships support research training experiences in new settings in order to maximize acquisition of new skills and knowledge. Therefore, postdoctoral fellowship applicants proposing training at their doctoral institution 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 fellowship applicant is required to provide detailed justification for the foreign training, including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than training in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Foreign training may require additional administrative reviews and will be considered for funding only when the scientific advantages are clear.

#### 11.2.2.6 NIH Employees & Other Federal Sponsorship (Federal Fellows)

Both civil service employees and PHS commissioned officers at NIH and other Federal laboratories are permitted to compete for predoctoral and postdoctoral fellowships. The proposed training should be primarily for career development rather than for the immediate research needs of NIH or the other Federal laboratory. When at an NIH laboratory, the employee's supervisor must disassociate himself/herself from the review and award process.

An individual at NIH or another Federal laboratory who is supported under an individual fellowship may not also hold an employee position with the Federal Government. Therefore, successful fellowship applicants for predoctoral or postdoctoral awards must either resign from NIH or the other Federal laboratory or take LWOP before activating the award. (There is no obligation or commitment by either the Federal agency or the fellow for future employment upon termination of the fellowship.)

Support provided for Federal fellows is similar to those at non-Federal sponsoring institutions; stipends, tuition (when applicable), and institutional allowance are provided. However, the administration and payment of these fellowships is unique. Specifics are noted in the applicable sections below.

#### 11.2.2.7 Individuals on Active Military Duty

NIH does not restrict career military personnel from applying for Kirschstein-NRSA individual fellowship awards while on active military duty. At the time of application, the fellowship applicant's branch of the military service should submit a letter endorsing 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.

### 11.2.3 Application Requirements and Receipt Dates

#### 11.2.3.1 Application

Each fellowship applicant must submit an application based on the application package provided as part of the FOA. Individual fellowship applications are submitted electronically through Grants.gov using an application package that combines form components from the SF424 (R&R) application with the PHS Fellowship Supplemental Form.

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The major emphasis of the application should be the research training experience and broadening of scientific competence. The AOR of the sponsoring institution agrees to secure and retain, but need not submit to NIH, the assurance signatures of the fellowship applicant and sponsor. The assurance of the fellowship applicant includes certification 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.

Fellowship applicants and sponsoring institutions must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements; research misconduct; the humane care and use of live vertebrate animals; the inclusion of women, minorities and 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 4, Public Policy Requirements, Objectives and Appropriation Mandates in IIA.)

### 11.2.3.2 eRA Commons Registration

All fellowship applicants and sponsoring institutions must be registered in the eRA Commons. The fellowship applicant must be assigned the "PI Role" in the eRA Commons. Only the PI Role will provide the fellowship applicant with the appropriate access in the eRA Commons to the application and review information. When a prospective fellowship applicant is submitting an application through a sponsoring institution that is different than their current institution, that individual must be affiliated with the sponsoring institution. Additional information on eRA Commons registration and affiliating individuals with different institutions can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.

### 11.2.3.3 Letters of Reference

As part of an application submission, at least three (but no more than five) letters of reference on behalf the fellowship applicant also must be submitted. Electronic submission of the fellowship application incorporates a separate, yet simultaneous electronic submission process for reference letters through the eRA Commons. Reference letters are submitted directly by the referee through the eRA Commons and not as part of the electronic application submitted through Grant.gov. Reference letters will be joined with the electronic application within the eRA system once an application completes the submission process. Applications that are missing the required letters may be delayed in the review process or not accepted. Applicants must carefully follow the instructions provided in Part I, Section 5.4 of the Individual Fellowship Application Guide found at: http://grants.nih.gov/grants/funding/424/index.htm. The Application Guide includes specific instructions to be sent to prospective referees.

### 11.2.3.4 Responsible Conduct of Research

All fellowship applicants must include a plan to obtain instruction in the responsible conduct of research. This section plan should document prior instruction in responsible conduct of research during the applicant's current career stage (including the date of last occurrence) and propose plans to receive instruction in responsible conduct of research. Such plans must address the five instructional components, format, subject matter, faculty participation, duration of instruction, and frequency of instruction, as outlined and explained below. The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the sponsor/mentor in responsible conduct of research instruction must be described. Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process.

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1. ***Format.*** Substantial face-to-face discussions between the fellow, other individuals in a similar training status and sponsors plus a combination of didactic and small-group discussions (e.g. case studies), are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable.

2. ***Subject Matter.*** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

a. conflict of interest – personal, professional, and financial

b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices

c. sponsor/fellow responsibilities and relationships

d. collaborative research including collaborations with industry

e. peer review

f. data acquisition and laboratory tools; data management, sharing and ownership

g. research misconduct and policies for handling misconduct

h. responsible authorship and publication

i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all aspects of responsible research conduct.

3. ***Faculty Participation.*** Sponsors and other appropriate faculty are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Sponsors may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors.

4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the fellow, sponsor and other appropriate faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Individual fellows are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Senior fellows may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the fellow

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award recipient is not actually supported by an NIH grant. This instruction must be documented in the submitted plan.

#### 11.2.3.5 Concurrent applications

An individual may not have two or more competing Kirschstein-NRSA individual fellowship applications pending review concurrently. In addition, CSR will not accept for review any application that is essentially the same as one already reviewed.

#### 11.2.3.6 Receipt Dates

Kirschstein-NRSA individual fellowship applications undergo a review process that takes 5 to 8 months. The annual schedule for application receipt, review, and award can be found in a specific Funding Opportunity Announcement and at http://grants.nih.gov/grants/funding/submissionschedule.htm.

### 11.2.4 Review

Each new and renewal application will be evaluated for scientific merit by an NIH SRG.

#### 11.2.4.1 Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood that the fellowship will enhance the fellowship applicant's potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria (as applicable for the project proposed).

Individual Fellowship programs are training awards and not research awards. Major considerations in the review are the candidate's potential for a productive career, the candidate's need for the proposed training, and the degree to which the research training proposed, the sponsor, and the environment will satisfy those needs.

#### 11.2.4.2 Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. The following review criteria are applicable primarily to F31 and F32 applications. For review criteria pertaining to other individual fellowship applications (e.g., F05, F30, F33), please refer to the specific FOA.

- ***Fellowship Applicant.*** Are the applicant's academic record and research experience of high quality? Does the applicant have the potential to develop as an independent and productive researcher in biomedical, behavioral or clinical science?

- ***Sponsor(s), Collaborator(s), and Consultant(s).*** Are the sponsor(s) research qualifications (including successful competition for research support) and track record of mentoring appropriate for the proposed fellowship? Are there (1) evidence of a match between the research interests of the applicant and the sponsor (including an understanding of the applicant's research training needs) and (2) a demonstrated ability and commitment of the sponsor to assist in meeting these needs? Are the qualifications of any collaborator(s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed research project?

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- ***Research Training Plan.*** Is the proposed research plan of high scientific quality, and does it relate to the applicant's training plan? Is the training plan consistent with the candidate's stage of research development? Will the research training plan provide the applicant with individualized and supervised experiences that will develop research skills needed for his/her independent and productive research career?

- ***Training Potential.*** Does the proposed research training plan have the potential to provide the fellow with the requisite individualized and supervised experiences that will develop his/her research skills? Does the proposed research training have the potential to serve as a sound foundation that will lead the fellow to an independent and productive career?

- ***Institutional Environment and Commitment to Training.*** Are the research facilities, resources (e.g. equipment, laboratory space, computer time, subject populations), and training opportunities adequate and appropriate? Is the institutional environment for the scientific development of the applicant of high quality, and is there appropriate institutional commitment to fostering the fellows' training as an independent and productive researcher?

### 11.2.4.3 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit but will not give separate scores for these items.

- ***Protections for Human Subjects.*** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

  For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

- ***Inclusion of Women, Minorities, and Children.*** When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

- ***Vertebrate Animals.*** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information, see http://grants.nih.gov/grants/olaw/VAChecklist.pdf.

- ***Biohazards.*** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

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- ***Resubmission Applications.*** When reviewing a Resubmission application the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

- ***Renewal Applications.*** When reviewing a Renewal application the committee will consider the progress made in the last funding period.

#### 11.2.4.4 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

- ***Training in the Responsible Conduct of Research.*** Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address the five Instructional Components (Format, Subject Matter, Faculty Participation, Duration of Instruction, and Frequency of Instruction) as detailed in Application Requirements—Responsible Conduct of Research in this chapter. Applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan.

- ***Select Agents Research.*** Reviewers will assess the information provided in this section of the application, including; 1) the select agent(s) to be used in the proposed research, 2) the registration status of all entities where select agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of select agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the select agent(s).

- ***Resource Sharing Plans.*** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

- ***Budget and Period Support.*** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research training.

- ***Foreign Sponsoring Institutions.*** For applications at foreign sponsoring institutions the reviewers will also assess whether the research training experience presents special opportunities for the fellowship applicant through the use of talent (e.g., mentor) resources, populations (if applicable), or training environment that are not readily available in the U.S. or augment existing U.S. talent and/or resources.

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#### 11.2.4.5 Secondary Level of Review

Kirschstein-NRSA individual fellowship applications receive a secondary level of review by IC staff. Criteria used in making award decisions include the SRG's recommendation concerning the overall merit of the application, the relevance of the application to the IC's research training priorities and program balance, and the availability of funds.

### 11.2.5 Notification of Action

Shortly after the initial review meeting, each fellowship applicant receives an e-mail indicating that the SRG recommendation/priority score is available in the eRA Commons. The fellowship applicant is also notified via an e-mail when the summary statement is available in the eRA Commons.

The PO may notify the fellowship applicant about the final review recommendation. All questions about initial review recommendations and funding possibilities should be directed to the designated IC PO, not to the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons. If the application is under consideration for funding, NIH will request any additional necessary information from the applicant. After all program and administrative issues have been resolved, the NoA will be issued for those selected for funding.

### 11.2.6 Period of Support

No individual may receive more than 5 years of aggregate Kirschstein-NRSA support at the predoctoral level and 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of Kirschstein-NRSA support from institutional research training grants and individual fellowships.

Any exception to the maximum period of support requires a waiver from the NIH awarding IC based on review of a justification from the individual and sponsoring institution. The AOR of the sponsoring institution must make the request in writing to the NIH awarding IC on behalf of the fellow, and must secure and retain, but need not submit to NIH, the fellow and sponsor's signatures. The request must specify the amount of additional support for which approval is sought. Individuals seeking additional support beyond the third year of postdoctoral support are strongly advised to consult with their PO before submitting a waiver request.

Some generally recognized categories under which NIH may grant exceptions include the following:

- ***Physicians/Clinicians.*** Individuals requiring additional time to complete training, either as participants in a combined M.D./Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training. An exception is contingent upon an assurance of the recipient's good academic standing and justified.

- ***Interruptions (Break in Service).*** Requests for additional time also will be considered if an event unavoidably alters the planned course of the research training, if the interruption has significantly detracted from the nature or quality of the planned research training, and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation, which prevent a fellow from effectively pursuing research training for a significant period of time. Requests for extension of support also will be considered if a short additional period would provide the fellow an opportunity to use an exceptional training resource directly related to the approved research training program.

Requests for additional time that do not arise from either of the above-described circumstances will be considered only if they are accompanied by an exceptionally strong justification.

### 11.2.7 Full-Time and Part-Time Training

All fellows are required to pursue their research training full time. Full-time is generally defined as devoting at least 40 hours per week to research training activities or as specified by the sponsoring institution in accordance with its own policies.

***Part-Time Training.*** While NRSA fellows are required to pursue training full-time, under certain circumstances, a written request may be submitted to the NIH awarding IC to permit less than full-time training.

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Written requests for part-time training will be considered on a case by case basis and must be approved by the NIH awarding IC in advance of each budget period. The circumstances requiring part-time training might include medical conditions, disability, or personal or family situations such as a child or elder care. Part-time training will not be approved to accommodate other sources of funding, job opportunities, clinical practice, clinical training, or responsibilities associated with the fellow's position at the sponsoring institution.

Each written request is submitted on behalf of the fellow by an AOR and must include documentation supporting the need for part-time training. The sponsoring institution must secure and retain, but need not submit to NIH, countersignatures of the fellow and sponsor prior to submission to NIH. The written request also must include an estimate of the expected duration of the period of part-time training and assurances that the fellow intends to return to full-time training when that becomes possible and intends to complete the proposed research training program. In no case will it be permissible for the fellow to be engaged in Kirschstein-NRSA support for less than 50 percent effort. Individuals who must reduce their commitment to less than 50 percent effort must take a leave of absence from Kirschstein-NRSA fellowship support.

NIH will issue a revised NoA with prorated stipend for the period of any approved part-time training. Part-time training may affect the rate of accrual or repayment of the service obligation for postdoctoral fellows.

## 11.2.8 Initiation of Support

### 11.2.8.1 Process

The NIH IC will notify the fellowship applicant of the intention to make an award and confirm the plans for the start of fellowship support. The individual may activate the fellowship on or after the issue date of the NoA up to the latest activation date shown in the NoA (generally 6 months after the award issue date). This timing allows the individual to make arrangements, such as the completion of degree requirements, coordination with the sponsor, and, if necessary, a move to the sponsoring institution. The latest activation date may be extended in unusual circumstances. Written requests for extensions should be submitted to the NIH awarding IC, by the AOR of the sponsoring institution. The sponsoring institution must secure and retain, but need not submit to NIH, signatures of the fellowship applicant and sponsor before the request is submitted to NIH.

The Activation Notice must be submitted to the NIH awarding IC as of the day the individual begins training. A Payback Agreement also must be completed and submitted but only by postdoctoral fellows in their first 12 months of Kirschstein-NRSA postdoctoral support. See Reporting Requirements—Activation Notice and Reporting Requirements—Payback Agreement in this chapter. A stipend may not be paid until the forms are submitted and the fellow begins training. If necessary for payroll purposes, the Activation Notice and Payback Agreement may be submitted up to 30 days before the start date. However, any change in the planned activation start date must be reported immediately to the sponsoring institution's business office and to the NIH awarding IC. If an award is conditioned upon completion of degree requirements, the fellow must submit, with the Activation Notice, proof of completion by the degree-granting institution.

Generally, individual fellowship support is approved for consecutive years of training. The initial award budget period is usually for 12 months. Subsequent periods of approved fellowship training are consecutive with the first year of support and are usually in 12-month increments (budget periods). Awards for less than 12 months will be prorated accordingly. If a fellow decides not to activate the award, or to terminate early, he or she must notify the institution's business office, the sponsor, and the NIH

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awarding IC immediately, in writing. NIH will make any necessary adjustments in the stipend and other costs, including the institutional allowance.

#### 11.2.8.2 Payment

***Domestic.*** Non-Federal sponsoring institutions receive an award for the stipend, institutional allowance, and tuition and fees (when applicable). The institution directly pays the fellow and disburses all other awarded costs.

***Federal Laboratories.*** Fellows training at Federal laboratories are paid stipends directly by the NIH awarding IC through NIH's OFM. Reimbursement to the fellow for appropriate expenditures from the institutional allowance also is coordinated by the NIH awarding IC and paid through OFM. Note, if a fellow is training at a facility that is Government-owned but Contract operated, this is not considered a Federal laboratory. As with other grants to these types of facilities, the sponsoring institution would be the contractor.

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

### 11.2.9 Allowable and Unallowable Costs

#### 11.2.9.1 Pre-award Costs

Pre-award costs to an individual fellowship are limited. Stipends and tuition and fees may not be charged to a fellowship award until a fellow has actually activated and the appropriate paperwork submitted to the NIH. Therefore, these costs may never be charged as pre-award to an individual fellowship. There are rare occasions when costs associated with the institutional allowance may be allowable as pre-award costs. Sponsoring institutions should consult with the NIH awarding IC when considering a pre-award cost.

#### 11.2.9.2 Stipends

A stipend is provided as a subsistence allowance for Kirschstein-NRSA fellows to help defray living expenses during the research training experience. It is not provided as a condition of employment with either the Federal government or the sponsoring institution. Stipends must be paid in accordance with stipend levels established by NIH, which are based on a 12-month full-time training appointment. In the event of early termination, the stipend will be prorated according to the amount of time spent in training. The sponsoring institution will submit a Termination Notice reflecting the early termination and the NIH awarding IC will issue a revised NoA to decrease approved funding. The sponsoring institution must base its calculations on the applicable stipend level provided by the NIH.

#### 11.2.9.3 Stipend Levels

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

General information related to stipends follows:

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

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- ***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 issue date of the fellowship award. In no case shall the stipend award exceed the current Kirschstein-NRSA stipend limit set by NIH. The level of Kirschstein-NRSA support will take into account concurrent salary support provided by the institution and the policy of the sponsoring institution. NIH support does not provide fringe benefits for senior fellows.

### 11.2.9.4 Institutional Allowance

NIH awards an institutional allowance to help support the costs of training. The specific levels of allowance for predoctoral and postdoctoral support, including those for individuals training at Federal laboratories, for-profit organizations, or foreign institutions, are published in the *NIH Guide for Grants and Contracts*. They also are available on the NIH Web site at http://grants.nih.gov/training/nrsa.htm#fellowhsips.

The institutional allowance is a fixed amount. Expenditures under institutional allowances are not subject to NIH prior approval requirements, and the institution is not required to account for these expenditures on an actual cost basis. Allowable uses of the Institutional Allowance are described below.

Except for fellows at Federal training sites, consistent with NIH policy governing the type of expenditures appropriate for the institutional allowance, the sponsoring institution authorizes the expenditure of the institutional allowance on behalf of the fellow according to the institution's policy. The institution is entitled to expend up to the full institutional allowance upon official activation of the award. However, if an individual fellow is not in a training status for more than 6 months of the award year, only one-half of that year's institutional allowance may be charged to the grant. The NoA will be revised and the stipend and institutional allowance balances must be refunded to NIH.

For fellows at Federal training sites, the NIH awarding IC authorizes the expenditure of the allowance. 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 IC and disbursed by OFM.

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- ***For-Profit Institutions.*** The allowance is intended to cover the costs of scientific meeting travel, health insurance, and books. Funds are paid directly to the sponsoring institution for disbursement to the fellow.

The following are guidelines for the use of the institutional allowance:

- ***Travel.*** Payment for travel to scientific meetings is appropriate when it is necessary for the individual's training and when the costs are incurred within the period of grant-supported training.

  For fellows at Federal laboratories, reimbursement of travel costs must be in accordance with applicable Federal travel regulations.

  Funds may not be expended to cover the costs of travel between the fellow's place of residence and the domestic training institution, except that the sponsoring institution may authorize the cost of a one-way travel allowance in an individual case of extreme hardship.

- ***Health Insurance.*** A fellow's health insurance is an allowable cost only if applied consistently to all individuals in a similar training status regardless of the source of support. Family health insurance is an allowable cost for fellows who have families and are eligible for family health insurance coverage at the sponsoring institution. Self-only health insurance is an allowable cost for fellows without families. Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy. Historically predoctoral fellowships included health insurance as part of the tuition and fees category. This is no longer the policy. For any fellowship (predoctoral and postdoctoral) that competed and was awarded in FY2007 and beyond, health insurance is awarded as part of the Institutional Allowance. Any fellowship that competed and was awarded prior to FY2007, health insurance will continue to be awarded as part of the Tuition and Fees category.

- ***Medical Liability and Other Special Insurance.*** Medical liability (malpractice) insurance or other special insurance is an allowable cost to NRSA grants only if nature of the research training requires such special insurance. For instance, medical liability would be allowable if the research training experience involves direct contact with patients or human subjects. In all cases, for the cost to be charged to the NRSA grant, it must be consistently required for all in a similar training status, regardless of the source of support. Special insurances that are routinely offered as optional employee benefits (such as disability insurance, life insurance, or workman's compensation insurance), are not normally allowable charges (see separate section on Employee Benefits) unless the nature of the research training requires such special insurance.

- ***Extraordinary Costs.*** Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring institution or accommodations for fellows who are disabled, as defined by the Americans with Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution in the application or as part of a special written request.

### 11.2.9.5 Tuition and Fees

Tuition and fees are provided under the following policy:

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- For individual predoctoral fellowships (**F30 and F31**), an amount equal to 60% of the level requested by the sponsoring institution, up to $16,000 per year, will be provided. If the program supports formally combined dual-degree training (e.g., M.D.-Ph.D., D.D.S.-Ph.D.), the amount provided will be up to $21,000 per year. Note the new policy moves health insurance into the Institutional Allowance budget category for predoctoral fellowships. This is now consistent with the treatment of this cost for postdoctoral fellowships

- For individual postdoctoral fellowships (**F32**) and individual senior fellowships (**F33**), an amount equal to 60% of the level requested by the applicant institution, up to $4,500 per year, will be provided. If the program supports postdoctoral individuals in formal degree-granting training, the amount provided will be up to $16,000 per year. For postdoctoral fellows, costs associated with tuition and fees are allowable only if they are required for specific courses in support of the research training. Health insurance is not included in this budget item because costs for it are to be charged as institutional allowance.

For fellowships that competed and were awarded before FY2007, tuition was awarded using a different formula. For predoctoral fellowships the tuition and fees category also included health insurance. When administering a fellowship that competed and was awarded prior to FY2007, consult the NIH awarding IC if there are questions concerning the awarding of tuition, fees, and health insurance.

### 11.2.9.6 Travel to Foreign Training Sites

For fellows at foreign training sites, in addition to the institutional allowance, awards may include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement shall not be influenced by factors of cost, convenience, or personal travel preference. For additional information regarding foreign travel, see Cost Considerations—Allowability of Costs/Activities-Selected Items of Cost-Travel/Employees in IIA.

### 11.2.9.7 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, life insurance, union dues, and unemployment insurance). Concerning union dues or other similar costs otherwise paid personally by the fellow; if a fellow requests the institution deduct such a cost from the stipend amount, the institution can provide the fellow such a service. However, in no case can such a deduction from the stipend be made automatically without the approval of the fellow.

### 11.2.9.8 Rebudgeting of Funds

Individual fellowship awards are formula based, generally restricted for the specific budget category of the award, and cannot be rebudgeted without prior written approval from the NIH awarding IC.

- Stipends must be expended using the stipend level provided in the award; no funds can be rebudgeted into the stipend category to accommodate a stipend level different from the established NIH level. When a fellowship terminates early, any unexpended stipends must be returned and cannot be rebudgeted into any other budget category.

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- Institutional allowance is a fixed amount of money with a number of allowable costs. In the rare case where institutional allowance may be unexpended, it can only be rebudgeted into the tuition and fees category when tuition and fees have been awarded.

- When tuition and fees is awarded, it is generally restricted and cannot be rebudgeted without prior written approval from the NIH awarding IC.

## 11.2.10 Supplementation of Stipends, Compensation, and Other Income

### 11.2.10.1 Stipend Supplementation

Kirschstein-NRSA fellows receive stipends to defray living expenses. Stipends may be supplemented by an institution from non-Federal funds provided this supplementation is without any additional obligation for the fellow. An institution can determine the amount of stipend supplementation, if any, it will provide according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may PHS funds be used for supplementation.

An individual may use Federal educational loan funds or VA benefits when permitted by those programs as described in Other Income: Educational Loans or GI Bill in this chapter.

### 11.2.10.2 Compensation

NIH recognizes that Kirschstein-NRSA fellows may seek part-time employment incidental to their training program to offset further their expenses. 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 IIA. In addition, compensation must be in accordance with organizational policies applied consistently to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation (salary, fringe benefits, and/or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. However, NIH expects that compensation from research grants will be for limited part-time employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant that supports the same research that is part of the fellow's planned training experience as approved in the Kirschstein-NRSA individual fellowship application.

***Stipend Supplementation & Compensation.*** Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved Kirschstein-NRSA training program. Fellowship sponsors must approve all instances of employment on research grants to verify that the circumstances will not detract from or prolong the approved training program.

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### 11.2.10.3 Other Income: Concurrent Benefits

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

### 11.2.10.4 Other Income: Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the VA (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation.

### 11.2.10.5 Other Income: NIH Loan Repayment Program

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

### 11.2.10.6 Taxability of Stipends

Section 117 of the Internal Revenue Code (26 U.S.C. 117) applies to the tax treatment of scholarships and fellowships. In general, degree candidates may exclude from gross income (for tax purposes) any amount used for qualified tuition and related expenses such as fees, books, supplies, and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are required to report as gross income any monies paid on their behalf for stipends or any course tuition and fees required for attendance.

The IRS and Treasury Department released regulations in January 2005 (Revenue Procedures 2005-11) clarifying the student exception to the FICA (Social Security and Medicare) taxes for students employed by a school, college, or university where the student is pursuing a course of study. NIH's understanding is that these final regulations do **not** apply to or impact Kirschstein-NRSA programs or awards.

The taxability of stipends in no way alters the relationship between Kirschstein-NRSA fellows and sponsoring institutions. Kirschstein-NRSA stipends are not considered salaries. In addition, recipients of Kirschstein-NRSA individual fellowships are not considered to be in an employee-employer relationship with NIH or the sponsoring institution solely as a result of the Kirschstein-NRSA award. The interpretation and implementation of the tax laws are the domain of the IRS and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

### 11.2.10.7 Form 1099

Although stipends are not considered salaries, these funds are subject to Federal and, sometimes, State income tax. Such income may be reported by the sponsoring institution on IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the sponsoring institution will be responsible for annually preparing and issuing IRS Form 1099 for fellows paid through the institution (fellows at domestic non-Federal institutions). Sponsoring institutions are not required to issue a Form 1099, but it is a useful form of documentation of funds received and it serves as a reminder to the fellow that some tax liability may exist. Fellows are reminded that, even if the sponsoring institution does not issue a Form 1099, they still are required to report Kirschstein-NRSA stipends. NIH will issue a Form 1099 for each fellow training at a Federal or foreign laboratory and receiving a stipend check from the NIH.

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## 11.2.11 Reporting Requirements

The submission of the forms described in this subsection is critical to establishing and paying stipends and other costs and determining possible payback service. All of these forms are available in PDF-fillable and Word formats at http://grants.nih.gov/grants/forms.htm. The NIH awarding IC may provide copies of applicable forms with the NoA or reference this Web site in the NoA.

### 11.2.11.1 Activation Notice

Immediately upon the initiation of training, the individual must complete and sign the Ruth L. Kirschstein Individual Fellowship Activation Notice (Form PHS 416-5), obtain the signature of the AOR, and forward the notice along with the Payback Agreement (required only for postdoctoral fellows in their first 12 months of Kirschstein-NRSA support) to the NIH awarding IC.

For Kirschstein-NRSA fellows paid directly by 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 IC.

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 IC immediately. Competing continuation awards must be activated on the day following the end of the last budget period of the previous award.

### 11.2.11.2 Payback Agreement

A Ruth L. Kirschstein National Research Service Award Payback Agreement (Form PHS 6031) that covers the initial 12 months of Kirschstein-NRSA postdoctoral support must be signed by each person who is to receive an individual postdoctoral fellowship. This form is not required if the individual has already received 12 months of postdoctoral Kirschstein-NRSA support under any Kirschstein-NRSA institutional research training grant or fellowship award. For details on Kirschstein-NRSA payback, see Payback Reporting Requirements in this chapter.

No Payback Agreement is required for predoctoral fellows.

### 11.2.11.3 Termination Notice

The Ruth L. Kirschstein National Research Service Award Termination Notice (Form PHS 416-7) (along with the Activation Notice and the NoA) is the basis for validating the total period of Kirschstein-NRSA support and establishing the amount of payback obligation for each Kirschstein-NRSA fellow. For individual fellowships, a reminder of this reporting requirement may be sent to the fellow by the NIH awarding IC before the scheduled termination date. For early terminations, the completed form will be required immediately upon receipt of notification from the fellow or an AOR. The termination notice must be submitted within 30 days of the termination date even if the fellow is not available for signature. In all cases, the information on the form must be verified by the sponsor and an institutional business official. The lack of timely and accurate information on this form could adversely affect data collected associated with aggregate NRSA support and the payback process. For additional information on early termination, see Changes in the Project below. Effective with Termination Notices submitted on/after January 1, 2011, all Termination Notices for individual fellowships are required to be submitted electronically using the eRA Commons xTrain application.

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### 11.2.11.4 Consecutive Support

If a fellow switches from one Kirschstein-NRSA grant mechanism to another (e.g., from an institutional research training grant to an individual fellowship or from one NIH IC to another), the requirement for payback service incurred is deferred until the total period of Kirschstein-NRSA support is completed. All fellowship applications are reviewed to determine if previous Kirschstein-NRSA support has been provided.

### 11.2.11.5 Progress Reports

Annual progress reports must be submitted for non-competing continuation support 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 Web site at http://grants.nih.gov/grants/forms.htm. Report form pages are available in PDF-fillable and Word 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 information is required as part of the Termination Notice.

### 11.2.11.6 Financial Reporting

An annual or final FFR to report expenditure information is not required for Kirschstein-NRSA individual fellowship awards. However, sponsoring institutions must still complete the quarterly reporting of Federal cash transactions using the FFR and submit that information directly to PMS.

## 11.2.12 Changes in the Project

Individual fellowship awards are made for training at a specific institution under the guidance of a particular sponsor. The approval of the NIH awarding IC is required for a transfer of the award to another institution, a change in sponsor, or a project change. As part of the approval process, if a fellow sponsored by a domestic non-Federal institution requests a transfer to another domestic non-Federal institution before the end of the current award year, the institutions are responsible for negotiating which will pay the stipend until the end of the current year. Disposition of the institutional allowance is also negotiable between the two sponsoring institutions. No Activation Notice is required from the new sponsoring institution.

Transfers involving Federal or foreign sponsoring institutions require unique administrative procedures and approvals. Because each transfer varies depending on individual circumstances, the sponsoring institution should contact the NIH awarding IC for specific guidance.

Any proposed change in the individual's specified area of research training must be reviewed and approved in writing by the NIH awarding IC to ensure that the training continues to be within the scientific scope of the original peer-reviewed application.

When the sponsor plans to be absent for a continuous period of more than 3 months, an interim sponsor must be named by the institution and approved in writing by the NIH awarding IC.

## 11.2.13 Other Terms and Conditions

### 11.2.13.1 Leave

***Vacations and Holidays.*** Kirschstein-NRSA fellows may receive the same vacations and holidays available to individuals in comparable training positions at the sponsoring institution. Fellows shall

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continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters generally is considered an active part of the training period and is not considered to be a vacation or holiday.

***Sick leave and Other Leave.*** Kirschstein-NRSA fellows may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for medical conditions related to pregnancy and childbirth.

***Parental Leave.*** Kirschstein-NRSA fellows may receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of a child when individuals in comparable training positions at the sponsoring institution have access to this level of 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 60 calendar days of parental leave, must seek approval from the NIH awarding IC for an unpaid leave of absence. A request letter must be submitted by the AOR on behalf of the fellow and must advise the NIH awarding IC of the dates of the leave of absence. Upon approval of the request, the NIH awarding IC will issue a revised NoA extending the ending date of the current budget/project period by the appropriate number of days or months of unpaid leave time. Recipients are precluded from spending award funds during the leave of absence; although continued coverage of health insurance would be allowable if in accordance with policy of the sponsoring institution.

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

### 11.2.13.2 Termination

NIH may terminate a Kirschstein-NRSA individual fellowship before its scheduled 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 IC must be notified immediately if a sponsoring institution wants to terminate an individual fellow or the fellow decides to terminate training before the scheduled expiration date.

If a fellow receives another NIH award, e.g., as a PD/PI on an R03, then the fellow is no longer eligible for the fellowship and the sponsoring institution should contact the awarding IC concerning early termination.

If a Kirschstein-NRSA fellowship is terminated early, the stipend must be prorated according to the amount of time spent in training, and the NoA will be revised downward. In addition, if the length of the

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final budget period was 6 months or less, the balance of any institutional allowance (at least one-half) must be refunded.

### 11.2.13.3 Publications and Sharing of Research Results

NIH supports the practical application and sharing of outcomes of funded research. Therefore, recipients of Kirschstein-NRSA fellowships should make the results and accomplishments of their activities available to the research community and to the public at large. The sponsoring institution should assist the fellow in such activities, including the further development of discoveries and inventions for furthering research and benefiting the public. No restrictions should be placed on the publication of results.

Kirschstein-NRSA fellows are encouraged to submit reports of their findings to the journals of their choice for publication. Responsibility for direction of the project should not be ascribed to NIH. However, NIH awarding IC support must be acknowledged by a footnote in language similar to the following: "This research was supported by the National Institutes of Health under Ruth L. Kirschstein National Research Service Award (number) from the (name of NIH IC)." In addition, Federal funding must be acknowledged as provided in Appropriation Mandates—Acknowledgment of Federal Funding in IIA.

The Public Access Policy requirements described in Administrative Requirements—Availability of Research Results—NIH Public Access Policy in IIA apply to articles that are authored or co-authored by NRSA fellows and arose from NIH Support. Information on publications is included as part of the annual progress report.

### 11.2.13.4 Copyright

Except as otherwise provided in the conditions of the award, when a publication or similar copyrightable material is developed from work supported by NIH, the author is free to arrange for copyright without approval of the NIH awarding IC. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce, translate, publish, and use and dispose of such materials, and to authorize others to do so for Federal government purposes.

### 11.2.13.5 Inventions and Patents

Fellowships funded primarily for educational purposes are not subject to invention reporting requirements nor does NIH have any rights to inventions under those awards (as specified in 37 CFR part 401.1(b)). Kirschstein-NRSA fellows training at NIH represent an exception to this policy. Those fellows are subject to the provisions of EO 10096 and NIH determines the disposition of rights to any invention conceived or first actually reduced to practice during the period of the fellowship.

### 11.2.13.6 Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award must be assigned to the sponsoring institution for disposition in accordance with established organizational policy. The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations, which, if permitted by organizational policy, may be retained by the fellow.

### 11.2.13.7 Public Policy Requirements and Objectives

All Public Policy Requirements, Objectives, and Other Appropriation Mandates discussed in IIA apply to Individual Kirschstein-NRSA fellowships when appropriate. Applicants must comply with policies and

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procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements and inclusion policies for women, minorities and children; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant DNA and human gene transfer research. See IIA for a complete list of applicable requirements.

It is the sponsoring institution's responsibility to ensure that a fellow has received the proper training/education and is properly supervised particularly in the areas of human subjects research, vertebrate animal research, and occupational safety programs.

Additional information and any application requirements can be found in the Individual Fellowship Application Guide available at: http://grants.nih.gov/grants/funding/424/index.htm.

Information provided below is in addition to that provided in IIA where unique circumstances might exist for individual fellowships.

#### 11.2.13.7.1 Human Subjects

***Indefinite Involvement.*** If the sponsoring institution has an approved FWA on file with OHRP but, at the time of application, plans for the involvement of human subjects are indefinite, the assurance number should be provided in the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

If the applicant organization does not have a FWA registered with the OHRP, that registration process must be completed prior to IRB approval.

#### 11.2.13.7.2 Vertebrate Animals

***Indefinite Involvement.*** If the sponsoring institution 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, the institution should indicate "Yes," to the involvement of Vertebrate Animals, 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 IC.

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 Individual Fellowship Application Guide or contact OLAW (see Part III).

### 11.2.13.8 Applicability of NIH Standard Terms of Award

Individual Fellowships are awarded under the NIH Standard Terms of Award however the provisions to extend the final budget period of a project period without additional funds and carryover of unobligated balances do not apply.

## 11.3 INSTITUTIONAL RESEARCH TRAINING GRANTS

### 11.3.1 General

NIH will award Kirschstein-NRSA institutional research training grants (T32, TL2, T34, and T35) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the institution, who are training for careers in specified areas of biomedical, behavioral, and clinical research.

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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. Training activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH Mission. The Kirschstein-NRSA 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.

## 11.3.2 Eligibility

### 11.3.2.1 Applicant Eligibility

A domestic, non-profit public or private organization may apply for a grant to support a research training program in a specified area(s) of research. Support for predoctoral, postdoctoral, or a combination of trainees may be requested. (Specific program announcements should be consulted for IC guidelines.) Support for short-term training positions for students in health-professional degree programs also may be requested as indicated in Short-Term Research Training in this subsection. Each applicant institution must submit an application using the research training forms and instructions (see Application Requirements and Receipt Dates in this subsection).

### 11.3.2.2 Research Areas

Kirschstein-NRSA institutional research training grants may be made for research training in areas that fall within the missions of the NIH ICs. Applications that do not address these areas will be returned. An increased emphasis has been placed on the research training of physicians. The HHS Secretary is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of 2 consecutive years of biomedical, behavioral, or clinical research training.

The applicant institution must have a strong research program in the areas proposed for research training and must have the staff and facilities required to carry out the proposed program.

Trainees appointed to the training program must have the opportunity to carry out supervised biomedical or behavioral research with the primary objective of developing or extending their research skills and knowledge in preparation for a research career.

### 11.3.2.3 Training Program Director/Principal Investigator(s)

The Training PD/PI must be an individual with the skills, knowledge, and resources necessary to organize and implement a high-quality research training program at the recipient organization. The Training PD/PI at the recipient organization will be responsible for the selection and appointment of trainees to the Kirschstein-NRSA research training grant and for the overall direction, management, and administration of the training program, including program evaluation, and submission of all required forms in a timely manner. In selecting trainees, the PD/PI must make certain that individuals receiving support meet the eligibility requirements set forth in this subsection.

More than one Training PD/PI (or multiple PD/PIs), may be designated on the application for training programs that require a team approach and therefore, clearly do not fit the single-PD/PI model (e.g., interdisciplinary of multidisciplinary training). The decision to apply for a single PD/PI or multiple PD/PIs is the responsibility of the investigators and applicant organizations, and should be determined and justified by the goals of the training program. Applications for grants with multiple PD/PIs require

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additional information, including the structure and governance of the PD/PI leadership team. In addition, the knowledge, skills and experience of the individual PD/PIs will be factored into the assessment of the overall scientific merit of the application. Multiple PD/PIs on a program share the authority and responsibility for leading and directing the training program, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization for the proper conduct of the program, including the submission of required reports.

Applications reflecting multiple PD/PIs must provide a Leadership Plan. The emphasis in the Leadership Plan should be on how it will benefit the research training program and the trainees.

A single Contact PD/PI must be designated for the purpose of communicating with the NIH, although other individuals may contact the NIH on behalf of the Contact PD/PI when necessary. Because training programs are intended to be coherent, NIH will not allocate the budget or training positions between multiple PD/PIs. Only a single award will be issued. Multiple PD/PI training programs should include reasonable numbers of PD/PIs and each should individual should be included for a specific purpose. Multiple-PD/PI applications should not include all mentors of the training grant as PD/PIs, except in unusual cases.

### 11.3.2.4 Research Training Program

A Kirschstein-NRSA institutional research training grant must be used to support a program of research training. It may not support studies leading to the M.D., D.D.S., D.V.M., or other clinical, health professional training except when those studies are a part of a formal combined research degree program, such as the M.D./Ph.D. Similarly, trainees may not accept Kirschstein-NRSA support for clinical training that is part of residency training leading to clinical certification in a medical or dental specialty or subspecialty. However, clinicians are permitted and encouraged to engage in Kirschstein-NRSA-supported full-time, postdoctoral research training even when that experience is creditable toward certification by a clinical specialty or subspecialty board.

Research trainees are expected to devote full time to the proposed research training. Full-time is generally defined as devoting at least 40 hours per week to the program or as specified by the sponsoring institution in accordance with its own policies. In order to fulfill the full-time requirement, trainees who also are training as clinicians must confine clinical duties to those that are an integral part of the research training experience.

### 11.3.2.5 Degree Requirements

#### 11.3.2.5.1 Predoctoral Training

Predoctoral research training is for individuals who have a baccalaureate degree 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 Kirschstein-NRSA institutional research training grant. Predoctoral research training must emphasize fundamental training in areas of basic biomedical and behavioral sciences.

#### 11.3.2.5.2 Postdoctoral Training

Postdoctoral research training is for individuals who have received a Ph.D., M.D., D.D.S., D.M.D., D.C., D.O., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.Sc., D.P.T., Pharm.D., N.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign institution. It is the responsibility of

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the grantee institution, not the NIH, to determine if a foreign degree is equivalent. Research training at the postdoctoral level must emphasize specialized training to meet national research priorities in the biomedical, behavioral, or clinical sciences.

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

### 11.3.2.5.3 Short-Term Research Training

Short-term research training includes the following:

- ***Students in Health Professional Schools.*** NIH offers two short-term training programs: those that are part of a traditional institutional research training grant (T32) and those that exclusively support short-term trainees (T35). Short-term research training experiences of 2 to 3 months are available to students in health-professional schools under both mechanisms. All short-term training must be full time. Unless otherwise stated, the requirements that apply to institutional research training grants also apply to short-term research training. Current stipend levels are published in *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 or semester in a program leading to a clinical doctorate or doctorate degree in a quantitative science, such as physics, mathematics, or engineering, before participating in the program. Individuals already matriculated in a formal research degree program in the health sciences, holding a research doctorate or master's degree, or a combined professional and research doctorate normally are not eligible for short-term training positions. In schools of pharmacy, only candidates for the Pharm. D. degree are eligible for short-term positions.

Short-term positions should be requested in the application. Short-term research training positions should last at least 8, but no more than 12, weeks. Health-professional students and students in the quantitative sciences selected for appointment should be encouraged to obtain multiple periods of short-term, health-related research training during the years leading to their degrees. Such appointments may be consecutive or may be reserved for summers or other "off-quarter" periods.

Since some NIH ICs do not support short-term research training positions under the T32 or support them on a limited basis only, applicants are urged to contact the appropriate NIH IC before requesting short-term research training positions as part of a T32 application.

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***T35.*** Several NIH ICs provide short-term research using a separate training grant mechanism (T35). The program intent and student eligibility requirements are similar to those indicated for the T32. However, since this Kirschstein-NRSA funding mechanism is used by only a few NIH ICs; interested applicants are encouraged to contact specific ICs for details.

#### 11.3.2.5.4 Pre-baccalaureate Training

NIH offers two distinct programs for pre-baccalaureate training under the auspices of the Kirschstein-NRSA undergraduate support mechanism (T34). Both programs are designed to support undergraduate 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 in the applicable FOA.

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, applicants should review the applicable FOA.

### 11.3.2.6 Citizenship

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Noncitizen nationals are individuals who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on 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 with a Conditional Permanent Resident status may be supported on NRSA training grants; however, as with all types of Permanent Resident status it is the grantee's responsibility to assure the individual remains eligible for NRSA support for the period of time of any appointment. Individuals on temporary or student visas are not eligible for Kirschstein-NRSA support.

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## 11.3.3 Application Requirements and Receipt Dates

### 11.3.3.1 Application

All applications for Kirschstein-NRSA institutional research training grants are submitted electronically through Grants.gov and use an application package that combines form components from the SF424 (R&R) application along with the PHS398 components. Application forms and instructions are provided as part of each FOA. Applicants should pay particular attention to the special instructions for institutional research training grants found in the SF424(R&R) Application Guide.

### 11.3.3.2 Receipt Dates

Several NIH ICs receive training grant applications three times each year; however, many ICs use only one or two receipt dates. Information on IC-specific receipt dates is available in the *NIH Guide for Grants and Contracts* in the NIH-wide T32 and T35 FOAs and FOAs issued by the individual NIH ICs or by contacting the appropriate NIH IC program official. For a list of the standard receipt dates and review cycle, see the http://grants.nih.gov/grants/funding/submissionschedule.htm. (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 requesting funding of $500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within the specific NIH ICs who has agreed to accept assignment of the application. This requirement is in place for all NIH ICs except those assigned to NIGMS, NICHD, NEI, NIDCR, or NINR; these ICs automatically accept all T32 applications regardless of the dollar amount, thus prior approval is not required. NIA waives this requirement for renewal and resubmission applications only. Applicants are strongly encouraged to contact the NIH IC if there are questions about the applicability of this policy

### 11.3.3.3 Special Program Considerations

The primary objective of the Kirschstein-NRSA program is to support graduate and postdoctoral research training to help ensure that a diverse and highly trained workforce is available to assume leadership roles related to the Nation's biomedical, behavioral and clinical research agenda.

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 PD/PIs should appoint only those individuals who are committed to a career in research and plan to remain on the training grant or in a non-Kirschstein-NRSA research experience for a minimum of 2 years in the aggregate. It also has been shown that transition to independent support is related to career success. Therefore, Training PD/PIs also should encourage and provide training in the skills necessary for postdoctoral trainees to apply for subsequent support through individual postdoctoral fellowships, mentored career development awards (K programs), or independent research project grants. When reviewing Kirschstein-NRSA institutional research training grant applications, peer reviewers will examine the training record to determine the average duration of training appointments for health-professional postdoctoral trainees and whether there is a history of transition to individual support mechanisms.

Studies also have shown that health professional trainees that train in combined programs with postdoctoral researchers with intensive research experience are more likely to apply for and receive research grant support. Programs located n clinical departments that focus on research training for individuals with the M.D. or other health-professional degrees should consider developing ties to basic

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science departments, or, if consistent with the goals of the program, modifying the program to include individuals with research doctorates. In these cases, applications should describe the basic science department's contribution to the research training experience and also indicate whether both health professional trainees and trainees with research doctorates will be included in the training program.

Training PD/PIs also must develop methods for ongoing evaluation of the quality and effectiveness of the training program. This should include plans to obtain feedback from current and former trainees to help identify weaknesses in the program and provide suggestions for program improvements as well as plans for assessing trainee's career development and progression, including publications, degree completion, and post-training positions. Evaluation results are to be included in competing continuation (renewal) applications and as part of the Final Progress Report.

Within the framework of the program's longstanding commitment to excellence and projected need for investigators in particular areas of research, attention must be given to recruiting trainees from racial or ethnic groups underrepresented in the biomedical, behavioral and clinical sciences, individuals with disabilities, and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research. Institutions are encouraged to identify candidates who will increase diversity on a national or institutional basis. NIH's requirements for diversity recruitment and retention are described below.

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### 11.3.3.4 Recruitment and Retention Plan to Enhance Diversity

The NIH recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences workforce. The NIH expects efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; to improve the quality of the educational and training environment; to balance and broaden the perspective in setting research priorities; to improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and to improve the Nation's capacity to address and eliminate health disparities.

Accordingly, the NIH continues to encourage institutions to diversify their student and faculty populations and thus to increase the participation of individual currently underrepresented in the biomedical, behavioral, clinical, and social sciences such as: individuals from underrepresented racial and ethnic groups; individuals with disabilities; and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research. Institutions are encouraged to identify candidates who will increase diversity on a national or institutional basis.

The NIH is particularly interested in encouraging the recruitment and retention of the following classes of candidates:

a. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see http://www.nsf.gov/statistics/nsf07308/content.cfm?pub_id=3633&id=3). In addition, it is recognized that under-representation can vary from setting to setting and individuals from racial or ethnic groups that can be convincingly demonstrated to be underrepresented by the grantee institution should be encouraged to participate in this program.

b. Individuals with disabilities, who are defined as those with a physical or mental impairment that substantially limits one or more major life activities.

c. Individuals from disadvantaged backgrounds who are defined as:

1. Individuals who come from a family with an annual income below established low-income thresholds. These thresholds are based on family size, published by the U.S. Bureau of the Census; adjusted annually for changes in the Consumer Price Index; and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels at HHS-Poverty Guidelines, Research and Measurement. For individuals from low income backgrounds, the institution must be able to demonstrate that such candidates have qualified for Federal disadvantaged assistance or they have received any of the following student loans: Health Professional Student Loans (HPSL), Loans for Disadvantaged Student Program, or they have received scholarships from the U.S. Department of Health and Human Services under the Scholarship for Individuals with Exceptional Financial Need.
2. Individuals who come from a social, cultural, or educational environment such as that found in certain rural or inner-city environments that have demonstrably and recently directly inhibited the individual from obtaining the knowledge, skills, and abilities necessary to develop and participate in a research career.

Recruitment and retention plans related to a disadvantaged background (C.1 and C.2) are most applicable to high school and perhaps undergraduate candidates, but would be more difficult to justify for individuals beyond that level of achievement. Under extraordinary circumstances the PHS may, at its discretion, consider an individual beyond the undergraduate level to be from a disadvantaged background. Such decisions will be made on a case-by-case basis, based on appropriate documentation.

NRSA training programs require all applicants to submit a recruitment and retention plan to enhance diversity. New applications must include such a plan and may wish to include data in support of past accomplishments. Renewal applications also must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous the funding period. Information must be included on successful and unsuccessful recruitment strategies including aggregate information on the distribution of:

- Students or postdoctorates who applied for admission or positions within the department(s)/program(s) relative to the research training grant;
- Students or postdoctorates who were offered admission to or a position within the department(s)/program(s);
- Students actually enrolled in the academic program relevant to the research training grant;
- Students or postdoctorates who were appointed to the research training grant.

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

Application without a diversity recruitment and retention plan will be considered incomplete and will not be reviewed.

A detailed account of experiences in recruiting individuals from underrepresented groups during the previous budget period also must be provided in the non-competing progress report submitted as a prerequisite to receiving non-competing continuation support.

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### 11.3.3.5 Training in the Responsible Conduct of Research

Every trainee supported by an NRSA training grant must receive instruction in the responsible conduct of research. All applications must include a plan to provide such instruction. The plan must address five components listed below. Renewal (Type 2) applications must, in addition, describe changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current instruction plan. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application. Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process.

1. ***Format.*** Substantial face-to-face discussions among the participating trainees; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs (see below), or unusual and well-justified circumstances.

2. ***Subject Matter.*** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

a. conflict of interest – personal, professional, and financial

b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices

c. mentor/trainee responsibilities and relationships

d. collaborative research including collaborations with industry

e. peer review

f. data acquisition and laboratory tools; management, sharing and ownership

g. research misconduct and policies for handling misconduct

h. responsible authorship and publication

i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all aspects of responsible research conduct.

3. ***Faculty Participation.*** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.

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4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the trainees and the participating faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the early career investigator level must receive instruction in responsible conduct of research at least once during this career stage. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the trainee is not actually supported by an NIH grant. This instruction must be documented in the submitted plan.

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.

## 11.3.4 Review

### 11.3.4.1 Overall

Each initial and competing continuation application will be evaluated for scientific merit by an NIH peer review group. Kirschstein-NRSA institutional research training grant applications also must be reviewed by the National Advisory Council or Board of the IC whose activities relate to the proposed research training.

### 11.3.4.2 Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the research training program to exert a sustained, powerful influence on the research field(s) involved. The scored review criteria and additional review criteria (as applicable for the research training program proposed) will be considered when determining the overall impact.

### 11.3.4.3 Review Criteria

Reviewers will consider each of the review criteria below in the determination of the scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific merit.

- ***Training Program and Environment.*** Are the research facilities and research environment conducive to preparing trainees for successful careers as biomedical scientists? Do the objectives, design and direction of the proposed research program ensure effective training? Is the proposed program of training likely to ensure that trainees will be prepared for successful and productive scientific careers? Do the courses, where relevant, and research training experiences address state-of-the-art science relevant to the aims of the program? Does the program provide training in inter- or multi-disciplinary research and/or provide training in state of the art or novel methodologies and techniques? Is a significant level of institutional commitment to the program evident? For

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applications that request short-term research training positions, is this aspect of the program well designed and, where appropriate, integrated with other aspects of the training program; are the numbers of short-term positions appropriate; and does the program include features to encourage short-term trainees to consider careers in health-related research?

- ***Training Program Director/Principal Investigator.*** Does the Training PD/PI have the scientific background, expertise, and experience to provide strong leadership, direction, management, and administration to the proposed research training program? Does the PD/PI plan to commit sufficient time to the program to ensure its success? Is sufficient administrative and research training support provided for the program? For applications designating multiple PD/PIs, is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees? Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and with the complementary expertise of each of the PD/PIs?

- ***Preceptor/Mentors.*** Are sufficient numbers of experienced preceptors/mentors with appropriate expertise and funding available to support the number and level of trainees proposed in the application? Do the preceptors/mentors have strong records as researchers, including successful competition for research support in areas directly related to the proposed research training program? Do the preceptors/mentors have strong records of training pre- and/or postdoctorates?

- ***Trainees.*** Is a recruitment plan proposed with strategies to attract high quality trainees? Are there well-defined and justified selection criteria and retention strategies? Is a competitive applicant pool in sufficient numbers to warrant the proposed size and levels (predoctoral, postdoctoral and/or short-term) of the training program in evidence? For applications that request short-term research training positions, does the program have the potential or evidence to recruit high quality, short-term trainees? For renewal applications, how successful has the program been in attracting and retaining individuals from diverse populations, including populations underrepresented in science?

- ***Training Record.*** How successful are the trainees (or for new applications, other past students/fellows in similar training) in completing the program? How productive are trainees (or for new applications other past students/fellows) in terms of research accomplishments and publications? How successful are trainees (or other past students/fellows) in obtaining further training appointments, fellowships, and career development awards? How successful are the trainees in achieving productive scientific careers, as evidenced by successful competition for research grants, receipt of honors or awards, high-impact publications, receipt of patents, promotion to scientific leadership positions, and/or other such measures of success? Does the program have a rigorous evaluation plan to review the quality and effectiveness of the training? Are effective mechanisms in place for obtaining feedback from current and former trainees and monitoring trainees' subsequent career development? For renewal applications, does the application describe the program's accomplishments over the past funding period(s); are changes proposed that would improve/strengthen the training experience? For programs that provide research training to health-professional doctorates, is there a record of retaining health professionals in research training or other research activities for at least two years? For applications that request short-term research training positions, are plans presented to follow the careers of short-term trainees and to assess the effect of the training program on subsequent career choices? What is the success in attracting students back for multiple appointments? What is the effect of the short-term component on the overall training program?

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- Individual Institutes and Centers may have additional specialized review criteria appropriate for their special initiatives and mission.

### 11.3.4.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- ***Protections for Human Subjects.*** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

  For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

- ***Inclusion of Women, Minorities, and Children.*** When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

- ***Vertebrate Animals.*** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

- ***Biohazards.*** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

- ***Resubmission Applications.*** When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

- ***Renewal Applications.*** When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

- ***Revision Applications.*** When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the

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committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

### 11.3.4.5 Additional Review Considerations

As applicable for the training program proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing the overall impact/priority score:

***Recruitment and Retention Plan to Enhance Diversity.*** Peer reviewer will separately evaluate the recruitment and retention to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment and retention of individuals from underrepresented groups.

The review panel's evaluation will be included in an administrative note in the summary statement. If the recruitment and retention plan to enhance diversity is judged to be unacceptable, funding will be withheld until a revised plan (and report) that addresses the deficiencies is received. Staff within the NIH IC, with guidance from its National Advisory Council or Board, will determine whether amended plans and reports submitted after the initial review are acceptable.

***Training in the Responsible Conduct of Research.*** Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address five Instructional Components (Format, Subject Matter, Faculty Participation, Duration and Frequency), taking into account the characteristics of institutional programs or the unique circumstances for short-term training programs. Plans and past record will be rated as **acceptable** or **unacceptable**.

***Select Agents Research.*** When applicable, reviewers will assess the information provided in this section of the application, including 1) the select agent(s) to be used in the proposed research; 2) the registration status of all entities where select agent(s) will be used; 3) the procedures that will be used to monitor possession use and transfer of select agent(s); and, 4) plans for appropriate biosafety, biocontainment, and security of the select agent(s).

***Budget and Period of Support.*** The reasonableness of the proposed budget and the requested period of support will be assessed in relation to the proposed research training program and the number of proposed trainees at the requested levels. The impact/priority score should not be affected by the evaluation of the budget.

For additional details, applicants also are encouraged to consult the application instructions, the NIH-wide T32 FOA, and specific IC FOAs.

### 11.3.4.6 National Advisory Council Review

Following initial peer review, applications undergo a second-level review by the appropriate NIH IC's National Advisory Council or Board. In addition to the assessment of the scientific and educational merit of the research training grant application, these advisory groups will consider the initial peer review group's comments on the plan for recruitment and retention to enhance diversity and the plan for instruction in the responsible conduct of research.

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## 11.3.5 Notification of Action

Shortly after the initial peer review meeting, the PD/PI will be sent an e-mail indicating that the SRG recommendation/priority score is available in the eRA Commons. The PD/PI is also notified via an e-mail when the summary statement is available in the eRA Commons. The PD/PI may be notified by the PO of the final review recommendation. Once all administrative and programmatic issues have been resolved, the NoA will be issued for applications selected for funding. Any questions concerning initial review recommendations and funding possibilities should be directed to the named PO, not to the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons.

## 11.3.6 Period of Support

### 11.3.6.1 Training Grants

Kirschstein-NRSA institutional research training grants may be made for competitive segments of up to 5 years and are renewable. Awards within an approved competitive segment normally are made in 12-month increments, referred to as budget periods; support for additional non-competitive years depends on satisfactory progress, submission of all required trainee-related documents, and availability of funds.

### 11.3.6.2 Trainees

Trainees under Kirschstein-NRSA institutional research training grants generally are appointed for full-time 12-month continuous periods. An appointment or reappointment period may begin any time during a particular budget period but may not begin before the budget period start date of the grant year. An appointment or reappointment may not exceed 12 months without prior approval by the NIH awarding IC. All trainees are required to pursue their research training on a full-time basis. Full-time is generally defined as devoting at least 40 hours per week to the program or as specified by the grantee in accordance with its own policies. Unless the NIH awarding IC furnishes other instructions, the amount of the stipend, tuition, and fees for each full period of appointment must be obligated by the 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 IC and then usually only to complete an ongoing program of training. An initial appointment of less than 9 months may be allowed as long as an assurance is included that the individual will be immediately reappointed in the subsequent year so that the cumulative continuous training period is at least 9 months.

***Part-Time Training.*** While Kirschstein-NRSA trainees are required to pursue research training on a full-time basis, under certain circumstances, a written request may be submitted to the NIH awarding IC to change a trainee appointment to less than full time. Such requests will be considered case-by-case and must be approved by the awarding IC before the applicable budget period. The circumstances requiring the part-time training might include medical conditions, disability, or personal or family situations such as a child or elder care. Part-time training will not be approved to accommodate use of other sources of funding, job opportunities, clinical practice, clinical training, or for other responsibilities associated with the trainee's position at the organization. In each case, the written request must be signed by an AOR and must include documentation supporting the need for part-time training. Countersignatures of the trainee and program director must be secured and retained by the grantee, but need not be submitted to NIH prior to submission to NIH. The written request also must include an estimate of the expected duration of the period of part-time training and assurances that the trainee intends to return to full-time training when that becomes possible and intends to complete the research training program.

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The stipend may be prorated in the grant award during the period of any approved part-time training. Part-time training also may affect the rate of accrual or repayment of the service obligation for postdoctoral trainees. In no case will it be permissible for the trainee to be engaged in Kirschstein-NRSA-supported research for less than 50 percent effort. Individuals who must reduce their commitment to less than 50 percent effort must take a leave-of-absence from a Kirschstein-NRSA training grant.

### 11.3.6.3 Kirschstein-NRSA Limitations

No individual trainee may receive more than 5 years of aggregate Kirschstein-NRSA support at the predoctoral level and 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from Kirschstein-NRSA institutional research training grants and individual fellowships.

Any exception to the maximum period of support requires a waiver from the NIH awarding IC based on review of a justification from the individual and the grantee organization. The AOR must make the request in writing to the NIH awarding IC on behalf of the trainee. The endorsement of the trainee's PD/PI certifying the need for additional support is retained by the grantee institution. The request must specify the amount and length of additional support for which approval is sought.

Some generally recognized categories under which NIH may grant exceptions include the following:

- ***Physicians/Clinicians.*** Individuals requiring additional time to complete training, either as participants in a combined M.D./Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training, may anticipate favorable consideration of a request for waiver of the time limitation. This action is contingent upon an assurance of the trainee's good academic standing and justified need for the exception to this policy.

- ***Interruptions (Break in Service).*** Requests for additional time also will be considered if an event unavoidably has altered the planned course of the research training, if the interruption has significantly detracted from the nature or quality of the planned research training, and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation that prevents a trainee from effectively pursuing research training for a significant period of time. Requests for extension of support also will be considered if a short additional period would provide the trainee an opportunity to use an exceptional training resource directly related to the approved research training program.

Requests that arise from circumstances other than those described above will be considered only if they are accompanied by an exceptionally strong justification.

## 11.3.7 Initiation of Support

The NoA is issued to the grantee organization, generally for a budget period of 12 months. A trainee may be appointed any time during the budget period for an appointment period of 9 to 12 months, without prior approval by the NIH awarding IC. A trainee appointment may not begin before the budget period start date.

At the time of the initial appointment and subsequent reappointment of trainees, the Training PD/PI must submit a Statement of Appointment for each trainee to the NIH awarding IC. In addition, a signed Payback Agreement must be submitted for each postdoctoral trainee who is in his/her first 12 months of

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Kirschstein-NRSA postdoctoral support. See Reporting Requirements—Statement of Appointment (Form PHS 2271) and Reporting Requirements—Payback Agreement (Form PHS 6031) in this chapter for specific information on required forms. The Statement of Appointment includes biographical data on the trainee and the stipend level for the period of appointment. The stipend is paid by the grantee organization directly to the trainee.

## 11.3.8 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 NoA .

### 11.3.8.1 Pre-Award Costs

While some pre-award costs are allowable to a training grant, grantees should note that stipends and tuition and fees may not be charged to a grant until a trainee has been officially appointed and the appropriate paperwork submitted to the NIH. Therefore, these costs may not be charged as pre-award to an institutional training grant. There are rare occasions when costs associated with training related expenses and/or trainee travel may be allowable as pre-award costs. Grantee institutions should consult with the NIH awarding IC when considering a pre-award cost.

### 11.3.8.2 Stipends

Trainees generally are supported for 12-month full-time training appointments for which they receive a stipend as a subsistence allowance to help defray living expenses during the research training experience. The stipend is not "salary" and is not provided as a condition of employment with either the Federal government or the 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.

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### 11.3.8.3 Trainee Tuition and Fees

Tuition and fees are allowable trainee costs only if such charges are applied consistently to all individuals in a similar training status at the organization, without regard to their source of support.

Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program and requires NIH awarding IC prior approval.

Tuition and fees are provided under the following policy:

- ***For Predoctoral Trainees.*** An amount equal to 60% of the level requested by the sponsoring institution, up to $16,000 per year, will be provided. If the program supports formally combined dual-degree training (e.g., M.D.-Ph.D, D.D.S.-Ph.D.), the amount provided will be up to $21,000 per year.

- ***For Postdoctoral Trainees.*** An amount equal to 60% of the level requested by the applicant institution, up to $4,500 per year, will be provided. If the program supports postdoctoral individuals in formal degree-granting training, the amount provided will be up to $16,000 per year.

Historically tuition and fees was awarded using different formulas and included health insurance as part of that budget category; however this is no longer the policy. Health insurance is now awarded as part of the Training-Related Expenses category. When administering a training that competed and was awarded prior to FY2007 and is still active in that particular competitive segment, consult the NIH awarding IC if there are questions concerning the awarding of tuition, fees, and health insurance.

Tuition and fees are awarded as a lump sum that can be allocated (without the prior approval of the NIH awarding IC) based on recipient needs.

### 11.3.8.4 Training-Related Expenses

Funds are provided to defray costs such as staff salaries, consultant costs, equipment, research supplies, staff travel, trainee health insurance (self-only or family as applicable), and other expenses directly related to the training program. Funds are requested and awarded as a lump sum on the basis of the predetermined amount per predoctoral and postdoctoral trainee approved for support. Levels are published in the *NIH Guide for Grants and Contracts*. Interested applicants should consult the program announcement regarding the specific level for programs such as the short-term training program, the MARC U*STAR program, or the COR program. Many of the costs allowable under Training-Related Expenses may cover global costs for an institutional training program where the Kirschstein-NRSA support covers only some of the participating trainees. For these types of global costs, institutions should allocate the appropriate portion of such costs to the training grant. Institutions are reminded that this budget category is a finite amount of money available to cover a variety of allowable costs. Institutions should be particularly mindful to apply core cost principles of allocation and consistent treatment.

***Health Insurance.*** Health Insurance (self-only or family) are allowable trainee related expenses only if such charges are applied consistently to all individuals in a similar training status at the organization, without regard to their source of support. Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy. Historically health insurance was awarded as part of the tuition and fees category. This is no longer the policy. For any training grant that competed and was awarded in FY2006 and beyond, health insurance is awarded as part of the Training Related Expenses category.

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***Medical Liability and Other Special Insurance.*** Medical liability (malpractice) insurance or other special insurance is an allowable cost to NRSA grants only if nature of the research training requires such special insurance. For instance, medical liability would be allowable if the research training experience involves direct contact with patients or human subjects. In all cases, for the cost to be charged to the NRSA grant, it must be consistently required for all in a similar training status, regardless of the source of support. Special insurances that are routinely offered as optional employee benefits (such as disability insurance, life insurance, or workman's compensation insurance), are not normally allowable charges (see separate section on Employee Benefits) unless the nature of the research training requires such special insurance.

***Staff Salaries.*** Institutions are reminded that applicable cost principles apply. For institutions covered by OMB Circular A-21, training programs may qualify as a "major project" where administrative salaries are allowable as a training-related expense.

***Speaker Fees.*** When speakers are part of program required for NSRA-supported trainees, a portion of such a cost could be charged as Training-related expenses.

***Meals.*** As stated in IIA, the cost of meals may be allowable if they are provided in conjunction with a meeting where the primary purpose includes the dissemination of technical information. A portion of such a cost could be charged as Training-related expenses. See Cost Considerations—The Cost Principles in IIA for specific guidance on the need institutional policies on consistent treatment and reasonableness.

***Extraordinary Costs.*** Under exceptional circumstances, which can include accommodating the disabilities of a trainee, it is possible to request organizational costs above the standard level. Requests for additional costs must be explained in detail and justified in the application. Consultation with NIH program staff in advance of such requests is strongly advised.

### 11.3.8.5 Trainee Travel Costs

If requested by the grantee, the NIH awarding IC may provide grant funds to cover the costs of trainee travel, including attendance at scientific meetings, which the organization determines is necessary to the individual's training. Trainees must be appointed to the training grants at time of the actual travel for this to be an allowable cost. Funds may not be expended to cover the costs of travel between the trainee's place of residence and the training institution, except that the 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 IC. Letters requesting such training may be submitted to the NIH awarding IC at any time during the appointment period.

### 11.3.8.6 Short-Term Training Costs

The 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.

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#### 11.3.8.7 Employee Benefits

Because Kirschstein-NRSA awards are not provided as a condition of employment with either the Federal government or the 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, life insurance, union dues, and unemployment insurance). Concerning union dues or other similar costs otherwise paid personally by the trainee, if a trainee requests the institution deduct such a cost from the stipend amount, the institution can provide the trainee such a service. However, in no case can such a deduction from the stipend be made automatically without the approval of the trainee.

#### 11.3.8.8 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 (when still awarded in the tuition and fees category), consortiums in excess of $25, 000, 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.

### 11.3.9 Rebudgeting of Funds

Funds may be rebudgeted only as follows:

- ***Trainee-Related Expenses.*** Rebudgeting of funds awarded in a lump sum for trainee-related expenses does not require NIH awarding IC prior approval.

- ***Trainee Costs.*** For rebudgeting purposes, trainee costs include funds awarded in the stipends or tuition/fees budget categories. These costs may not be used for other purposes except under unusual circumstances and then only with the prior approval of the NIH awarding IC. Unless otherwise restricted, rebudgeting into or within the stipends and tuition/fees is allowable without prior approval of the NIH awarding IC. Note during the transition period for the new tuition policy, health insurance is included as a trainee cost only when still awarded as part of the tuition and fees budget category. For those training programs awarded under the new policy, health insurance is included in the trainee-related expenses category; thus the rebudgeting policies of that category would apply.

- ***Trainee Travel.*** For rebudgeting purposes, trainee travel is not considered a trainee cost and, therefore, may be rebudgeted into any other budget category without prior approval of the NIH awarding IC.

### 11.3.10 Stipend Supplementation, Compensation, and Other Income

#### 11.3.10.1 Stipend Supplementation

Grantees may supplement stipends from non-Federal funds provided the supplementation is without any additional obligation for the trainee. An organization can determine what amount of stipend supplementation, if any, will be provided according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar training status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. An individual may use Federal educational loan funds or VA benefits when permitted by those programs as described in

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Educational Loans or GI Bill below. Under no circumstances may PHS funds be used for supplementation.

### 11.3.10.2 Compensation

NIH recognizes that student trainees 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 IIA. In addition, compensation must be in accordance with organizational policies consistently applied to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation (salary, fringe benefits, and/or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. However, NIH expects that compensation from research grants will be for limited part-time employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant that supports the same research that is part of the trainee's planned training experience as approved in the Kirschstein-NRSA institutional research training grant application.

***Stipend Supplementation & Compensation.*** Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the trainee's approved Kirschstein-NRSA training program. Training PD/PIs must approve all instances of employment on research grants to verify that the circumstances will not detract from or prolong the approved training program.

### 11.3.10.3 Other Income: Concurrent Benefits

An individual may not receive support under a Kirschstein-NRSA institutional research training grant concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the Kirschstein-NRSA award.

### 11.3.10.4 Other Income: Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the VA (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation. In the case of the MARC-U*STAR program, funds from a Pell grant may be accepted as well.

### 11.3.10.5 Other Income: NIH Loan Repayment Program

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

### 11.3.10.6 Taxability of Stipends

Section 117 of the Internal Revenue Code (26 U.S.C. 117) applies to the tax treatment of scholarships and fellowships. Degree candidates may exclude from gross income (for tax purposes) any amount used for qualified tuition and related expenses, such as fees, books, supplies, and equipment, required for courses of instruction at a qualified educational organization. Nondegree candidates are required to report as gross

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income any monies paid on their behalf for stipends or any course tuition and fees required for attendance.

The IRS and Treasury Department released regulations in January 2005 (Revenue Procedures 2005-11) clarifying the student exception to the FICA (Social Security and Medicare) taxes for students employed by a school, college, or university where the student is pursuing a course of study. NIH's understanding is that these final regulations do **not** apply to or impact Kirschstein-NRSA programs or awards.

The taxability of stipends in no way alters the relationship between Kirschstein-NRSA trainees and 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.

#### 11.3.10.7 Form 1099

Although stipends are not considered salaries, the funds are subject to Federal and, sometimes, State taxes. The grantee organization may report such funds 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 funding 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.

### 11.3.11 Carryover Authority

The NIH Standard Terms of Award apply to Kirschstein-NRSA institutional research training grants; however, in most cases, grantees must obtain awarding IC prior approval to carry over funds. Some NIH awarding ICs have also waived this prior approval requirement for training grants. The NoA for a Kirschstein-NRSA institutional research training grant will specify whether or not the grantee must obtain the prior approval of the awarding IC to carry over funds.

### 11.3.12 Program Income

Applicants for NIH research grants, including Kirschstein-NRSA institutional research training grants, are required to include in their grant applications an estimate of the amount and source of program income expected to be generated as a result of the project for which support is being sought. See Administrative Requirements—Management Systems and Procedures—Program Income in IIA for policies that govern the disposition and reporting of program income.

### 11.3.13 Reporting Requirements

The submission of the forms described in this subsection is critical to establishing the payment of stipends and other costs and determining possible payback service. Failure to submit the required forms in a timely manner may result in an expenditure disallowance or a delay in any continuation funding. All of these forms are available in PDF-fillable and MS Word formats at http://grants.nih.gov/grants/forms.htm.

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### 11.3.13.1 Statement of Appointment (Form PHS 2271)

The grantee must submit a PHS 2271 to the NIH awarding IC before or at the start of each trainee's appointment or reappointment. No 2271s can be submitted until after the NoA for the respective budget period has been issued. Effective with any PHS2271 submitted January 1, 2011 and beyond, grantees are required to submit the PHS 2271 data electronically using the eRA Commons xTrain application. More information on xTrain is available at http://era.nih.gov/services_for_applicants/other/xTrain.cfm.

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. A complete Social Security Number must be included on the Payback Agreement. The PD/PI and the organizations' financial officials should coordinate the information reported on the Statement of Appointment. It should be treated as a financial document for obligating funds (stipends), which later are reflected on the Termination Notice and as part of the total costs in the 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/PI to the NIH awarding IC on an amended PHS 2271 at the time of the change. Interim revisions for any appointment initially processed via xTrain, must also be submitted through xTrain.

***Consecutive Support.*** If a trainee switches from one Kirschstein-NRSA mechanism to another (e.g., from an individual fellowship to a training grant) or from one NIH awarding IC to another, the requirement for payback service incurred is deferred until the total period of Kirschstein-NRSA support is completed. All Statement of Appointment forms are reviewed to determine if previous Kirschstein-NRSA support has been provided.

### 11.3.13.2 Payback Agreement (Form PHS 6031)

A Payback Agreement that covers the initial 12 months of Kirschstein-NRSA postdoctoral support must be signed by each postdoctoral trainee. If the individual has already received 12 months of postdoctoral support under any Kirschstein-NRSA training grant or fellowship award, this form is not required. For details on Kirschstein-NRSA payback, see Payback Requirements in this chapter.

No Payback Agreement is required for predoctoral or prebaccalaureate trainees.

### 11.3.13.3 Termination Notice (Form PHS 416-7)

The Termination Notice (along with the PHS 2271 Statement of Appointment form) is the basis for validating the total period of Kirschstein-NRSA support and establishing the amount of payback obligation, if any, for each Kirschstein-NRSA trainee. The PD/PI is responsible for submitting a Termination Notice for each trainee within 30 days of the end of the total period of support even if the trainee is not available for signature. In all cases, the information on the form must be verified by the program director and an institutional business official. The lack of timely and accurate information on this form could adversely affect data collected associated with aggregate NRSA support and the payback process. Effective with any Termination Notice submitted January 1, 2011 and beyond, grantees are required to submit the PHS 416-7 data electronically using the xTrain application. More information on xTrain is available at http://era.nih.gov/services_for_applicants/other/xTrain.cfm.

No Termination Notice is required for prebaccalaureate (T34) trainees.

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#### 11.3.13.4 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 Web site at http://grants.nih.gov/grants/forms.htm. Progress report form pages are available in PDF-fillable and MS Word 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 IC within 90 days after the end of grant support.

#### 11.3.13.5 Federal Financial Report (FFR)

An annual FFR is required for all Kirschstein-NRSA institutional research training grant awards no later than 90 days after the end of the calendar quarter in which the budget period ended. This report will document the financial status of the grant according to the official accounting records of the 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 reported as unliquidated obligations. The same principal may apply to trainee health insurance when an institution can truly obligate the full appointment amount at the start of the appointment.

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 in IIA).

### 11.3.14 Closeout

The Closeout requirements included in IIA apply (see Administrative Requirements—Closeout—Final Reports). In addition, Termination Notices for all trainees are required.

### 11.3.15 Changes in the Project

Changes in the program objectives as they relate to the area of research training for which the grant was approved require prior approval of the NIH awarding IC.

If the PD/PI is expected to be absent more than 3 months, plans for the conduct of the program during his or her absence must be approved in writing by the NIH awarding IC. Any proposed change of PD/PI must be requested by the grantee organization and be approved in writing by the NIH awarding IC following review of the nominee's qualifications and re-evaluation of the project in light of the proposed change.

Kirschstein-NRSA institutional research training grants may not be transferred from one domestic organization to another except under the most unusual circumstances. Such a change generally will be approved by the NIH awarding IC only if all of the major benefits attributable to the original grant can be transferred and there is no negative impact on trainees active in the program.

### 11.3.16 Other Terms and Conditions

#### 11.3.16.1 Leave

***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

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during vacations and holidays. At academic institutions, the time between semesters or academic quarters generally is considered an active part of the training period and is not considered to be a vacation or holiday.

***Sick Leave and Other Leave.*** Trainees may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for the medical conditions related to pregnancy and childbirth.

***Parental Leave.*** Trainees may receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of a child when individuals in comparable training positions at the grantee organization have access to this level of paid leave for this purpose. Either parent is eligible for parental leave. The use of parental leave must be approved by the Training PD/PI.

***Terminal Leave.*** A period of terminal leave is not permitted, and payment may not be made from grant funds for leave not taken.

***Unpaid Leave.*** Individuals requiring extended periods of time away from their research training experience, that is, more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding IC for an unpaid leave of absence. Approval for a leave of absence must be requested in advance by an AOR on behalf of the trainee.

During a leave of absence, documentation to suspend the period of appointment must be completed by submitting an amended Statement of Appointment and a Termination Notice. These forms should be submitted to the NIH awarding IC at the beginning of the leave. Upon resumption of Kirschstein-NRSA support, the reappointment must be documented on another Statement of Appointment form.

### 11.3.16.2 Termination

NIH may terminate a Kirschstein-NRSA institutional research training grant before its normal 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 IC immediately. In such cases, NIH will issue a revised NoA to specify the changed period of support and to show prorated trainee stipends, depending on the amount of time spent in training.

### 11.3.16.3 Publications and Sharing of Research Results

NIH supports the practical application and sharing of outcomes of funded research. Therefore, PD/PIs and trainees should make the results and accomplishments of their Kirschstein-NRSA institutional training grant activities available to the research community and to the public at large. The grantee organization should assist trainees in these activities, including further development of discoveries and inventions for furthering research and benefiting the public. No restrictions should be placed on the publication of results.

Trainees are encouraged to submit reports of their findings for publication to the journals of their choice. Responsibility for direction of the project should not be ascribed to NIH. However, NIH IC support must

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be acknowledged by a footnote in language similar to the following: "This investigation was supported by the National Institutes of Health under Ruth L. Kirschstein National Research Service Award (number) from the (name of NIH IC)." In addition, Federal funding must be acknowledged as provided in Appropriation Mandates—Acknowledgment of Federal Funding in IIA.

The Public Access Policy requirements described in Administrative Requirements—Availability of Research Results—NIH Public Access Policy in IIA apply to articles that are authored or co-authored by NRSA trainees and arose from NIH Support. Information on trainee publications is included as part of the annual progress report.

### 11.3.16.4 Copyright

Except as otherwise provided in the NoA, when a publication or similar copyrightable material is developed from work supported by NIH, the author is free to arrange for copyright without the approval of the NIH awarding IC. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce, translate, publish, and use and dispose of such materials, and to authorize others to do so for Federal government purposes.

### 11.3.16.5 Inventions and Patents

All Kirschstein-NRSA institutional research training grants and other funding agreements awarded primarily for educational purposes are not subject to invention reporting requirements nor does NIH have any rights to inventions under those grants and agreements (as specified in 45 CFR part 74.24(h) and in 37 CFR part 401.1(b)).

### 11.3.16.6 Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award may not be retained by the trainee. Such fees must be assigned to the grantee organization for disposition in accordance with NIH policy on program income (see Administrative Requirements—Management Systems and Procedures—Program Income in IIA). The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations. If permitted by organizational policy, these fees may be retained by the trainee.

### 11.3.16.7 Public Policy Requirements and Objectives

All Public Policy Requirements, Objectives, and Other Appropriation Mandates discussed in IIA apply to Kirschstein-NRSA Institutional programs when appropriate. Applicants must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements and inclusion policies for women, minorities and children; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant DNA and human gene transfer research. See IIA for a complete list of applicable requirements.

Additional information and any application requirements can be found in the SF424 (R&R), Section 8. Supplemental Instructions for Preparing Institutional Ruth L. Kirschstein-NRSA Applications.

Information provided below is in addition to that provided in IIA where unique circumstances might exist for institutional training programs.

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#### 11.3.16.7.1 Human Subjects

***Indefinite Involvement.*** If the applicant organization has an approved FWA or other applicable assurance on file with OHRP but, at the time of application, plans for the involvement of human subjects are indefinite, the assurance number should be provided in the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

In many instances, trainees supported by Kirschstein-NRSA institutional research training grants will be participating in research supported by research project grants for which the IRB review is already completed or an exemption is already designated. This review or exemption designation is sufficient, provided the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation. The grantee institution must ensure that trainees have received the proper training/education in human subjects research.

#### 11.3.16.7.2 Vertebrate Animals

***Indefinite Involvement.*** If the applicant organization has an approved 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, the organization should indicate "Yes," to the involvement of Vertebrate Animals and include the animal welfare Assurance of Compliance number. If an award is made, vertebrate animals may not be involved until verification of the IACUC approval date has been submitted to the NIH awarding IC.

In many instances, trainees supported by institutional research training grants will be participating in research supported by research project grants for which the IACUC review already is completed. This review is sufficient, provided the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC review dates. The institution must ensure that trainees are enrolled in the institution's animal welfare training and occupational health and safety programs for personnel who have contact with animals, as appropriate. It is also the institution's responsibility to ensure that trainees are properly supervised when working with live vertebrate animals.

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

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## 11.4 PAYBACK REQUIREMENTS

### 11.4.1 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.

## 11.4.2 Implementation

The incurrence of a payback obligation for an NRSA recipient is solely dependent upon when NRSA support was received. This section reflects current Payback requirements for individuals supported on/after June 10, 1993. Payback requirements for individuals supported before June 10, 1993 are found on the Payback Service Center Home Page.

***Predoctoral Recipients.*** For predoctoral trainees no payback obligation is incurred. Thus a Payback Agreement Form (PHS 6031) is not required.

***Postdoctoral Recipients.*** For individuals receiving postdoctoral support under individual fellowships or institutional research training grants, a payback obligation is incurred for the first 12 months of Kirschstein-NRSA support. However, the 13th and subsequent months of postdoctoral NRSA supported research training serves to pay back this obligation month by month. A Payback Agreement (PHS 6031) is required but only for the initial 12-month postdoctoral support period.

***Short-Term Training.*** Any individual receiving support for predoctoral short-term training does not incur a payback obligation; however, postdoctoral short-term training does incur a payback obligation. Support for short-term training accrues, along with any subsequent NRSA postdoctoral support, until the first 12 months is established. At that point, the 13th and subsequent months of support serve to offset the obligation month by month. If subsequent postdoctoral support is not received, the individual has an obligation to pay back in the traditional manner.

## 11.4.3 Payback

Once a Termination Notice has been submitted and accepted, the NIH awarding IC determines if a payback obligation exists. When a trainee or fellow must pay back, the Termination Notice and related documents are forwarded to the NIH Kirschstein-NRSA Payback Service Center (PSC). PSC personnel are NIH's experts in Kirschstein-NRSA payback requirements. The PSC administers the payback activities of all of the NIH ICs. The authorities related to payback normally delegated to the IC are delegated to the Chief, Kirschstein-NRSA PSC. The PSC retains all records until an obligation is satisfied, and then transfers closed records to the Federal Records Center.

Most Kirschstein-NRSA recipients eventually fulfill their payback obligation by engaging in activities that are determined to be acceptable service. Some recipients fulfill their obligation via financial payback. On rare occasions, the payback obligation is waived.

As indicated in Payback Reporting Requirements—Implementation in this subsection, the amount of a payback obligation incurred is solely dependent on the total period of support and the laws in effect when the Kirschstein-NRSA support was received.

### 11.4.3.1 Service Payback

#### 11.4.3.1.1 Definitions

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

- ***Research.*** Research is defined as an activity that involves designing experiments, developing protocols, and collecting and interpreting data. In addition, review of original research or administration of original research that includes providing scientific direction and guidance to research may be acceptable if a doctoral degree and relevant research experience is required for individuals filling such positions. Such research can be conducted in an academic, government,

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commercial, or other environment in either a foreign or domestic setting. In addition, when consistent with the cumulative amount, type, and frequency of research or research training experiences, functions that involve analytic or other technical activities conducted in direct support of research, as defined above, will also satisfy the service payback obligation.

- ***Teaching.*** Teaching is an instructional activity that takes place in an organized educational or other instructional environment. Activities classified as teaching are generally carried out in a formal didactic setting, but other activities will be considered if they are consistent with the certifying institution's policy on the definition of teaching responsibilities. Such teaching can be conducted at universities, professional schools, research institutes, teaching hospitals, primary schools, secondary schools, or colleges. When calculating hours of teaching per week, it is permissible to include 3 hours of preparation time for each hour of direct instruction. Acceptable teaching activities must have a biomedical or health-related relevance.

- ***Health-Related 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.

#### 11.4.3.1.2 Time Commitment

All acceptable activities must be undertaken for periods that average at least 20 hours per week. Total employment in such activities averaging less than 20 hours per week cannot be counted toward fulfilling the obligation except in cases of disability or other pressing personal or family circumstances, such as 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.

#### 11.4.3.1.3 Initiation of Payback Service

Service payback obligations for postdoctoral recipients may be discharged by

- receiving an equal number of months of postdoctoral Kirschstein-NRSA support beginning in the 13th month of such postdoctoral Kirschstein-NRSA support, or

- engaging in an equal number of months of health-related research, training, or teaching averaging more than 20 hours per week.

#### 11.4.3.1.4 Source of Funding

There is no restriction on the source of funds supporting an individual's service payback activity. An individual could be supported by a PHS grant or any non-Kirschstein-NRSA Federal or non-Federal source. Unpaid service also is permitted.

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#### 11.4.3.1.5 Timing of Service Obligation

An individual must begin to undertake the payback service requirement within 2 years after the termination date of the individual's Kirschstein-NRSA support unless an extension of time to begin payback has been approved by the PSC (see Payback—Extensions of Payback—Extensions of the 2-Year Period to Initiate Payback below).

### 11.4.3.2 Financial Payback

#### 11.4.3.2.1 Policy and Principal Calculation

If an individual does not perform payback service, the Federal government shall be entitled to recover certain costs. The amount the United States is entitled to recover depends on when support was received. Calculation formulas take into account the total amount paid the individual (see Interest and Interest Rate Calculation below), less any obligation already fulfilled through service or legislative allowance when applicable. The total paid an individual under an institutional research training grant or individual fellowship award at a domestic, non-Federal sponsoring institution is considered to be the stipend only. The total paid an individual under a fellowship award at a foreign sponsoring institution includes the payment for the round-trip travel costs. The total paid an individual under a fellowship award at a Federal sponsoring institution includes any money expended from the institutional allowance provided for such purposes as health insurance, travel, tuition, and fees.

#### 11.4.3.2.2 Interest and Interest Rate Calculation

NIH computes interest on the principal amount beginning on the date the United States became entitled to recover stipends. The interest rate is the rate fixed by the Secretary of the Treasury after considering prevailing consumer rates of interest. Accordingly, interest may accrue on any Kirschstein-NRSA obligation if the 2-year grace period has passed, if deferment has expired, or if service has terminated before completion of the payback obligation. The Department of the Treasury certifies Kirschstein-NRSA interest rates quarterly. Interest is computed on a 360 day-a-year basis and is applied through the date of receipt. Any outstanding amount will continue to bear interest at the initial rate set by the Secretary of the Treasury until financial payback is complete.

The date that sets the applicable rate of interest depends on the type of Kirschstein-NRSA account received for collection. If financial payback is voluntary, the signature date of the notification of voluntary payback is the date that determines the interest rate as well as the initiation of the 3-year repayment period. If financial payback is involuntary, the date that sets the interest rate and the 3-year repayment period is the date of expiration of the 2-year period following the termination of Kirschstein-NRSA support. For example, if during June 2007, OFM received an account reflecting January 31, 2005, as the termination date of NRSA support, the Federal government, lacking any documentation to the contrary, becomes entitled to financial payback effective February 1, 2005. The rate of interest applicable is determined based on the February 1, 2005, date, and the total NRSA obligation is required to be fulfilled by January 31, 2008.

The amount to be recovered financially, as determined from the Termination Notice plus applicable interest, shall be paid to the United States within the 3-year period following such date.

### 11.4.3.3 Extensions of Payback

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

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#### 11.4.3.3.1 Extensions of the 2-Year Period to Initiate Payback

An extension of the 2-year period to initiate payback may be requested in the Annual Payback Activities Certification form. Indication of valid plans to initiate payback soon after the 2-year grace period may be good reason to grant an extension.

#### 11.4.3.3.2 Basis for Extensions or Break in Service

The PSC may extend the period for undertaking payback service or permit breaks in continuous service. These determinations are based on the following criteria:

- An extension or break in service is necessary so the individual may complete 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, for example, completing residency training where clinical teaching or research are not an integral part of the training, or seeking employment that would fulfill the payback requirements.

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

### 11.4.3.4 Waiver

#### 11.4.3.4.1 Policy

The authorizing legislation and the implementing regulation (42 CFR part 66) permit exceptions to certain requirements under the Act. NIH may waive, in whole or in part, the payback obligation, upon determination that compliance by the individual is impossible or would involve substantial hardship, and enforcement of the individual's obligation would be against equity and good conscience.

#### 11.4.3.4.2 Waiver Criteria

Requests for waivers should be made in writing to the PSC and should include an explanation of the need for the waiver according to the following criteria:

- Compliance by an individual will be deemed impossible if the individual is permanently, and totally disabled.
- In determining whether compliance would involve substantial hardship to the individual and would be inequitable, the PSC will consider the individual's
    - financial resources and obligations at the time of request for a waiver and

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- estimated future financial resources and obligations.

- In rare cases, the following also may be considered:
  - Reasons for the individual's failure to complete the requirements within the prescribed period, such as personal problems;
  - Extent to which the individual has engaged in payback activities;
  - Sufficiency of training to qualify the individual to perform such activities;
  - Lack of employment opportunities appropriate to the individual's education and training;
  - Any other extenuating circumstances.

Any obligation of any individual toward payback will be canceled upon death of the individual.

## 11.4.4 Certification of Payback Activities

### 11.4.4.1 Annual Payback Activities Certification (Form PHS 6031-1)

### 11.4.4.2 Annual Certification

Payback service is certified through the use of the Kirschstein-NRSA APAC (PHS 6031-1). Individuals with an outstanding payback obligation must complete an APAC annually until their payback obligation is fulfilled.

If an individual has a payback obligation, an APAC is sent by the PSC approximately one year after the completion of Kirschstein-NRSA support. Payback service may be initiated within the first 12 months of termination even though trainees and fellows have up to 24 months to initiate payback. There is no penalty to those individuals who do not initiate payback within the first 12 months; however, it is critical that they complete an APAC form to ensure contact is maintained and addresses are current.

The individual will report on the APAC the activity in which 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.

### 11.4.4.3 Change of Address

Any change in the mailing address of a Kirschstein-NRSA recipient must be reported promptly to the PSC until the service obligation is fully discharged. Notification of changes can be made by letter, telephone, fax, or e-mail to NRSAPaybackCenter@mail.nih.gov.

### 11.4.4.4 Breaks in Kirschstein-NRSA Support

Sometimes a trainee/fellow will have a period of non-Kirschstein-NRSA support between two Kirschstein-NRSA awards. An appropriate activity performed during this period of time may count for payback purposes toward the first Kirschstein-NRSA award. If the nonsupport period is 6 months or longer, the individual receives an APAC form through the regular mechanism. However, if the break is less than 6 months, an APAC will not be mailed automatically. If acceptable payback service was

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performed during the break, the individual may complete an APAC, which can be obtained from the NIH Web site at http://grants.nih.gov/grants/forms.htm.

#### 11.4.4.5 National Health Service Corps

A Kirschstein-NRSA recipient may have also been a National Health Service Corps (NHSC) scholar. Legislative changes effective October 26, 2002, eliminated the previously existing concurrent payback option. 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 Kirschstein-NRSA payback service.

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# 12 RESEARCH CAREER DEVELOPMENT ("K") AWARDS

## 12.1 GENERAL

This chapter includes general information about research career development awards (CDAs), also known as "K" awards. It supplements the general information found in IIA that applies to all NIH awards.

The objective of the NIH career development programs is to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs. Among NIH ICs, a variety of programs are available for scientists who require additional mentored or independent experience in a productive scientific environment in order to further develop their careers in independent biomedical, behavioral and clinical research.

For mentored programs, support is provided to cover protected time for supervised career development experiences with a goal of leading to research independence. Independent (non-mentored) programs foster the development of outstanding scientists and enable them to expand their potential to make significant contributions to a field of research.

### 12.1.1 Background

The research CDA program was established in 1961 to enable investigators who have demonstrated research potential to develop further their research careers. The program is authorized by sections 301, 402 and 405 of the PHS Act, 42 U.S.C. 241, 282 and 284. In general, CDAs provide up to five years of salary support and guarantee substantial protected time to engage in research and related activities. The award is available to persons who have demonstrated independent research accomplishments but need additional experience to establish or sustain an independent research program.

## 12.2 TYPES OF CAREER DEVELOPMENT AWARDS

### 12.2.1 General

NIH offers a wide variety of CDAs: mentored awards to individuals, including unique career transition programs; non-mentored awards to individuals (mid-career and senior stages), and institutional programs that provide mentored experiences for multiple individuals who are selected by the institution. Some CDAs are linked to other types of NIH awards. Applicants are encouraged to review the FOA for information about IC-specific utilization of the wide variety of CDAs. Specific questions may be directed to the appropriate NIH scientific/research staff or grants management staff named in the FOA.

Further information about specific NIH CDAs is found at the K Kiosk http://grants.nih.gov/training/careerdevelopmentawards.htm.

### 12.2.2 Individual Mentored Career Development Awards

Individual mentored CDAs (e.g. K01, K07 (developmental), K08, K22, K23, K25, K99/R00) provide support for a sustained period of "protected time" (generally three, four, or five years) for intensive research career development under the guidance of an experienced mentor or sponsor in the biomedical,

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behavioral, or clinical sciences. Through the sustained period of research career development and training provided by mentored CDAs, recipients are expected to gain the skills and experience necessary for independent and productive research careers. Mentored CDAs are not renewable, nor are they transferable from one individual to another. No-cost extensions in time are permitted; however, all terms and conditions, including appointment and minimum effort requirements, remain during the extension period.

Generally, mentored CDA programs are covered by NIH-wide Parent FOAs. In addition, some ICs may issue IC-specific FOAs for specialized programs. Specific program requirements for each mentored CDA program are found in the FOAs. Some programmatic information is provided below for programs with unique policies.

#### 12.2.2.1 Mentor

Individual mentored CDA applications require the candidate to identify a mentor (sometimes referred to as a sponsor) with extensive and appropriate research experience. The candidate must name a primary mentor/sponsor, who, together with the candidate is responsible for the planning, direction, and execution of the program. The mentor should be recognized as an accomplished investigator in the proposed research area; have a track record of success in training independent investigators; and should have sufficient independent research support to cover any costs of the proposed research project in excess of the allowable costs of the CDA award. Candidates may have co-mentors/sponsors as appropriate to the goals of the program. Whenever possible and appropriate, women, individuals from diverse racial and ethnic groups, and individuals with disabilities are encouraged to be involved as mentors to serve as role models.

### 12.2.3 Career Transition Awards

In general, the career transition award programs (K22 and K99/R00) provides protected time through salary and research support to facilitate the transition of postdoctoral individuals or junior faculty in mentored positions to research independence.

#### 12.2.3.1 K22

In general, the K22 program supports two phases of research: 1) a mentored phase (2 years); and, 2) an independent phase (up to 3 years), for a total of up to 5 years of combined support. Applicants for K22 programs need not be affiliated with an applicant institution, e.g., NIH intramural scientists. Planning, direction, and execution of the proposed K22 award are the responsibility of the candidate. Often K22 programs are targeted towards individuals conducting research at NIH intramural laboratories to provide funds to facilitate a transition to an independent research position at an extramural institution. Only a few ICs support K22 programs and each has specific eligibility criteria and award provisions. There is no parent FOA.

When the applicant is an intramural scientist, NIH issues a provisional award letter and the actual NoA is issued after identifying a suitable position at an extramural research institution. The position may include continuation of a postdoctoral segment.

#### 12.2.3.2 Pathway to Independence Award (K99/R00)

The objective of the Pathway to Independence Award (K99/R00) is to assist postdoctoral investigators in transitioning to a stable independent research position with independent research funding. The K99/R00 program offers a two-phase award, generally providing up to a total of 5 years of support. Phase I (K99) provides support for up to 2 years of intensive, mentored research career development; Phase II (R00) provides support for up to 3 years of independent research, contingent on securing an independent

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research position. Phase II is also contingent upon an administrative review and approval by the awarding IC of a transition application.

#### 12.2.3.2.1 Eligibility

The K99/R00 program has several unique eligibility criteria that are not generally applicable to other CDA programs.

- U.S. citizens and non-U.S. citizens with the skills, knowledge and resources necessary to carry out the proposed research and career development activities are eligible to apply;
- K99/R00 applicants must not have more than 5 years of postdoctoral research training at the time of initial application or resubmission;
- NIH intramural scientists are eligible to apply. If selected for funding, the K99 phase is supported by the NIH IC intramural laboratory in which the candidate conducts research. The R00 phase is supported via an extramural award once an acceptable position at an extramural organization is secured.

#### 12.2.3.2.2 K99 Phase

Generally the K99 phase is for 2 years; however, award recipients may transition earlier than 2 years when the recipient has been offered an acceptable position. Some NIH awarding ICs have issued specific guidance regarding the length of time in the K99 phase before transition may occur; therefore, recipients are advised to contact the awarding IC if early transition is being considered.

Since the K99 and R00 phases are awarded independently, a no-cost extension can be executed should additional time be needed to complete the goals of the K99 phase. All terms and conditions of the K99/R00 award (including minimum effort requirements) remain in effect when the grant is in a no-cost extension.

Automatic carryover from the K99 phase to the R00 phase is allowed provided the K99 phase was funded by extramural support. The K99 grantee should include a note on the FSR regarding the carryover to the R00 phase.

#### 12.2.3.2.3 Transition to the R00 Phase

The K99 award recipient is required to secure a tenure track, full-time assistant professor position or equivalent in order to transition to the R00 independent phase. Transition to the R00 phase is not guaranteed. The transition application for the R00 phase is administratively reviewed by NIH staff and is not peer reviewed by a study section. There should not be any delay between the K99 phase and the R00 phase. R00 award recipients will be expected to compete successfully for independent R01 support from the NIH during the R00 phase of the award.

Additional information on the K99/R00 and the FOA are found on the New Investigators Program web page under Pathway to Independence Award:
http://grants.nih.gov/grants/new_investigators/pathway_independence.htm.

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### 12.2.4 Individual Non-mentored (Independent) Career Development Awards

Independent (non-mentored) CDAs (e.g. K02, K05, K07 leadership, K24) provide protected time for scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers. Independent CDAs are intended to foster the development of outstanding scientists and to enable them to expand their potential to make significant contributions to their field of research. Some Independent CDAs also require the candidates to serve as research mentors for junior researchers.

Candidates for independent CDAs must have a doctoral degree and independent, peer-reviewed support at the time the award is made. Some of the participating NIH ICs require candidates to have an NIH research grant from their IC at the time of application. Other NIH ICs will accept candidates with peer-reviewed, independent research support from other sources.

Planning, direction, and execution of the proposed career development program and research project are the responsibility of the applicant and sponsoring institution. Independent CDAs are not transferable from one PD/PI to another. Non-mentored awards are sometimes renewable.

### 12.2.5 Institutional Scientist Development Programs

The institutional mentored research scientist development program (K12 and KL2) provides support to an institution for the development of independent basic or clinical scientists. The goal is to enhance research career development for individuals (known as 'scholars') selected by the institution who are training for careers in specified research areas. A specified number of scholar positions are awarded in a K12. The K12 is solicited only by IC-specific FOAs. Although the K12 is subject to NIH Standard Terms of Award, the carryover of unobligated balances from one budget period to the next generally requires prior written approval. K12 awards are generally not transferable to another institution. When institutional mentored research development programs are incorporated as part of a Clinical and Translational Science Award Consortium the KL2 activity code is used.

The Clinical Research Curriculum Award (K30) is awarded to an institution to stimulate the inclusion of high-quality, multidisciplinary, didactic training as part of the career development of clinical investigators. It supports the development and/or improvement of core courses designed as in-depth instruction in the fundamental skills, methodologies, and theories necessary for the well-trained, independent, clinical researcher.

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## 12.3 ELIGIBILITY

Eligibility can vary depending on the type of award and may even vary by NIH IC within a particular program. However, there are some eligibility criteria which are consistent across all CDA programs and these criteria are discussed in this section. Candidates are always strongly encouraged to carefully review the eligibility criteria in a specific FOA and to contact the scientific/research and/or grants management contacts in the relevant IC prior to preparing an application to discuss issues of eligibility. These contacts are listed in the individual FOA for each CDA.

### 12.3.1 Eligible Institutions

Applications for CDAs may be submitted on behalf of the candidate by any domestic for-profit or non-profit public or private institution/organization such as universities, colleges, hospitals, and laboratories to

support a research program in a specified area(s) of research. Foreign institutions are not eligible to apply for CDAs.

### 12.3.2 Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research as the candidate (called the PD/PI) is invited to work with his/her organization to develop an application for a CDA program. Individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are always encouraged to apply for NIH programs. Multiple PD/PI applications are not accepted for individual CDAs; institutional CDAs should check the FOA for the allowability of Multiple PD/PIs.

For mentored CDA programs, candidates who are well-established in their fields are considered ineligible. Some indications of having achieved this status are tenure or the equivalent, a substantial publication record or considerable research support that already requires commitment of a major part of the candidate's time. Applicants who meet one or more of these criteria must provide justification in the application that they are not already established in their field.

### 12.3.3 Degree Requirements

Degree requirements for CDAs are outlined in the specific FOA. Applicants are generally required to hold a research or health–professional doctoral degree or its equivalent; eligibility for some CDAs is limited to only applicants with health professional doctoral degrees.

### 12.3.4 Citizenship

For CDA programs other than the K99/R00 program, only U.S. citizens, non-citizen nationals or individuals lawfully admitted for permanent residence at the time an offer of an award is made, are eligible for this award. Individuals on temporary or student visas are not eligible to apply for a CDA unless they have begun the process for becoming a permanent resident and expect to be admitted as a permanent resident by the earliest possible award date. In an application package, on the PHS398 Career Development Award Supplemental Form, the option of selecting “Non-citizen with temporary visa” is applicable to K99/R00 candidates only.

Noncitizen nationals are individuals who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on his/her passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the applicant organization’s responsibility to follow up and ensure that the candidate receives the I-551 before the 6-month expiration date.

An individual expecting to be admitted as a permanent resident by the earliest possible award date listed in the career award FOA may submit an application recognizing that no award will be made until legal verification of permanent resident status is provided to the NIH. The submission of documentation concerning permanent residency is not required as part of the initial application.

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Applicants who have been lawfully admitted for permanent residence, i.e., have a Permanent Resident Card or other legal verification of such status, should check the Permanent Resident of U.S. box in Section 3. Citizenship of the PHS398 Career Development Award Supplemental Form. Applicants who have applied for and have not yet been granted admission as a permanent resident or have been granted Conditional Permanent Residency Status should also check the same box.

If a candidate's citizenship status changes after submission of an application, the new status should be reported in the candidate's Personal Profile in the eRA Commons.

In all cases involving any type of Permanent Residency status, when an application is selected to receive an award, prior to any award being issued, a notarized statement will be required that documents that a licensed notary has seen the candidate's valid Permanent Resident Card or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. In all cases where Permanent Residency status is involved, it is the responsibility of the grantee institution to assure the individual remains eligible for the project period of the award.

## 12.3.5 Type of Appointment

Candidates for all CDA programs must have a full-time appointment at the applicant institution both at the time of application and award. With prior approval from the NIH, award recipients may hold part-time appointments for limited periods during the course of their awards (see Temporary Adjustments to the Full-Time Institutional Appointment Requirement below). Full-time or part-time is as defined by applicant institutional policy.

Candidates who hold additional appointments with an independent clinical practice plan, the VA or other organizations should contact the scientific/research and/or grants management contact in the relevant IC prior to preparing an application to discuss their eligibility. Responsibilities outside of the applicant organization appointment are not restricted; however, these types of additional appointments cannot be used to meet the full-time appointment requirement nor the effort requirement discussed below. If a candidate has a dual appointment, they must also have a full-time appointment at the applicant institution in order to qualify for a CDA.

### 12.3.5.1 Temporary Adjustments to the Full-Time Institutional Appointment Requirement

In January 2009 a new policy was adopted allowing a temporary adjustment of the full-time requirement for awarded CDAs under certain circumstances. At the time of the award, the candidate must meet the full-time appointment requirement (as well as any minimum effort requirement); however, awardees may request a temporary reduction in their appointment to less than full-time (but not less than three-quarter time) for a period not to exceed 12 continuous months during the CDA award project period. Circumstances requiring such a change in appointment status might include personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. Permission to change appointment status will not be approved to accommodate job opportunities, clinical practice, clinical training, or joint appointments.

When requesting approval to change to a part-time appointment status, the awardee must continue to commit at least 75% effort (of the part-time appointment) to research and career development activities. The awardee is encouraged to consider increasing his/her percent effort to greater than 75% (e.g., 85%) to compensate for the anticipated effect of the part-time appointment on the awardee's career progress.

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On behalf of the K awardee, the grantee institution must submit a request and documentation to the NIH awarding IC supporting the need for a reduced faculty appointment and assuring the institution's continuing commitment to the scientific and research career development of the awardee. The request should justify reducing the appointment to less than full-time status and must describe the anticipated impact of the requested change on his/her career progress during the remainder of the award period. In addition, the awardee must submit assurance of his/her intention to return to a full-time faculty appointment as soon as possible. The mentor must provide a revised mentoring plan and specifically describe updated milestones for the awardee's progression to independence. Lastly, a revised statement of institutional commitment to the awardee must ensure continued "protected time" and describe additional support that will assist the awardee to continue to make progress toward his/her goals during the requested period of the reduced appointment. During the period of reduced appointment, the salary and other costs supported by the award will be reduced accordingly. Requests must be submitted by the grantee institution to the awarding Institute or Center (IC) where they will be considered on a case-by-case basis.

For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of the award, a request for reduction in the appointment must address the impact of this action on the awardee's ability to make sufficient progress to meet the goals of the program. For example, a K99 awardee must describe how the request will affect the awardee's ability to transition to the R00 phase of the award.

The new policy also allows awardees to temporarily reduce the level of effort devoted to the CDA award; that policy is described below in Level of Effort. While these 2 policies are similar in overall goals, an awardee may not simultaneously request a reduction in appointment status from full-time to part-time AND a reduction in percent effort to less than 75%.

## 12.3.6 Level of Effort

In addition to the full-time appointment requirement described above, mentored and non-mentored CDA candidates are required to devote and maintain a minimum level of effort to the award. During a no-cost extension, the recipient is required to maintain any effort minimum and can only reduce his/her effort with prior approval of the awarding IC.

Candidates who hold additional appointments with an independent clinical practice plan, the VA or other organizations may not use these additional appointments to meet the minimum effort requirement. Responsibilities outside of the applicant organization appointment are not restricted; however, they also cannot be used to meet any minimum effort requirement. If a candidate has a dual appointment, they must also have a full-time appointment at the applicant institution and be able to meet the minimum effort requirement as part of that full-time appointment in order to qualify for a CDA. Candidates should contact the scientific/research and/or grants management contact in the relevant IC prior to preparing an application to discuss their eligibility.

### 12.3.6.1 Mentored CDAs

Mentored CDA candidates are required to devote a minimum commitment equivalent of 9 calendar person months (75% or their full-time appointment at the applicant institution) to the career development and research objectives of the program specified in each FOA. The remaining 3 person months (25% effort), if applicable, can be divided among other research, clinical, and teaching activities only if these activities are consistent with the goals of the mentored CDA, i.e., the candidate's development into an independent investigator.

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Mentored awardees are allowed to devote complementary effort without salary support on other research grants that include related research between the CDA and the research grant. In such cases where there is scientific overlap, the percent effort on the research grant is subsumed within the required effort of the CDA. The related research must be consistent with the goals and objectives of the CDA.

### 12.3.6.2 Concurrent Support

Provided they remain in a mentored status, mentored CDA recipients in the final two years of their support period are permitted to reduce the level of effort required for the CDA when they have competed successfully for peer-reviewed research awards from NIH or any Federal agency, if programmatic policy of the other Federal agency allows such an arrangement. Recipients are encouraged to obtain funding from NIH or other Federal sources either as a PD/PI on a competing research grant award or cooperative agreement or as a project leader on a competing multi-project award.

Budgets for a competing research grant or a subproject on a multi-project grant should request appropriate amounts for the salary and associated costs for the CDA recipient's effort. At the time the research grant is awarded the effort required on the CDA may be reduced to no less than 6 person months (50% full-time professional effort at the grantee organization) and replaced by effort and corresponding salary from the research award so that the total level of research commitment remains at 9 person months (75% full-time professional effort) or more for the duration of the mentored CDA. This policy applies to the following mentored CDA activity codes: K01, K07 (developmental), K08, K22, K23, and K25, as well as individuals mentored through institutional K12 or KL2 awards. To be eligible for salary support from peer-reviewed research awards from any Federal agency:

- The CDA recipient must be one of the named PD/PIs on a competing NIH research grant application (R01, R03, R15, R21, R34, or equivalent application from another Federal agency) or a sub-project director on a competing multi-component research or center grant or cooperative agreement application (P01, P50, U01, etc. or an equivalent application from another Federal agency).

- The CDA must be active when the competing research grant application is submitted.

- The CDA must be in its final two years before the reduction in effort to 6 person months (50% full-time professional effort) is permitted.

For submissions to NIH, a letter must accompany the research grant application from the chair of the mentored award recipient's department or other responsible institutional official providing: (1) evidence that the recipient will continue to focus on the development of his/her research career; (2) will continue to have access to his/her mentor; and (3) that the recipient's total level of research effort will be maintained and protected at a minimum of 9 person months (75% full-time professional effort). For submissions to other Federal agencies, this type of institutional commitment letter is strongly encouraged; however, applicants should check with that agency for guidance on the allowability of such a letter.

When a mentored CDA recipient obtains independent support, as described above, the NIH awarding IC supporting the CDA will adjust the level of effort committed to the CDA to no less than 6 person months (50% effort) consistent with maintaining total research effort at 9 person months or 75% or more of the full-time appointment. NIH may adjust the total salary and fringe benefits amounts awarded to the CDA if consistent with the adjusted level of effort. If necessary, the K award may also be adjusted to avoid any additional budget overlap.

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### 12.3.6.3 Non-mentored CDAs

Established investigators on independent (non-mentored) CDAs are generally required to devote a minimum of 3-6 person months (25-50% effort) conducting research and research career development related activities during the period of the award. Some independent CDAs allow and may require more than 6 person months (50% effort). For example, K02 recipients are required to devote 9 person months (75% effort) to research.

Generally, an independent or leadership awardee may receive additional salary support from other NIH/PHS grants for effort above the CDA and there are no limitations to receiving other salary support. However, K02 recipients may not receive salary from other NIH/PHS grants. Where applicable, specific policies are noted in the FOA. The candidate must be able to demonstrate that the requested period of salary support and protected time will foster his/her career and capacity to contribute to the specified field.

### 12.3.6.4 Temporary Adjustments to the Percent Effort Requirement

At the time of the CDA award, the candidate must still meet the applicable effort requirement (as well as the full-time appointment requirement); however, under certain circumstances, awardees may request a temporary reduction in their effort for a period not to exceed 12 continuous months during the award project period. For programs that require a 75% effort minimum (equivalent to 9 person months), an awardee can request a reduction to no less than 50%. Circumstances requiring such a change in effort might include personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. Permission to temporarily reduce effort will not be approved to accommodate job opportunities, clinical practice, clinical training, or joint appointments.

On behalf of the K awardee, the grantee institution must submit a request and documentation to the NIH awarding IC supporting the need for reduced effort and assuring the institution's continuing commitment to the scientific and research career development of the awardee. The request should justify reducing effort and must describe the anticipated impact of the requested change on his/her career progress during the remainder of the award period. In addition, the awardee must submit assurance of his/her intention to return to 75% effort as soon as possible. The mentor must provide a revised mentoring plan and specifically describe updated milestones for the awardee's progression to independence. Lastly, a revised statement of institutional commitment to the awardee must ensure continued "protected time" and describe additional support that will assist the awardee to continue to make progress toward his/her goals during the requested period of the reduced appointment. During the period of reduced effort, the salary and other costs supported by the award may be reduced accordingly. Requests must be submitted by the grantee institution to the awarding Institute or Center (IC) where they will be considered on a case-by-case basis.

This option is not available for Independent CDAs that require only 25-50% effort; e.g., K07 leadership, K05, and K24.

While this temporary adjustment in effort policy is similar to the policy described above allowing a temporary adjustment in the full-time appointment requirement, awardee may not simultaneously request a reduction in appointment status from full-time to part-time AND a reduction in percent effort to less than 75%.

## 12.3.7 Prior Research Support

Applicants who have previously served as the PD/PI on a NIH R03 or R21 grant or non-PHS equivalent at the time of application may apply for a mentored CDA (except for the K99/R00 program).

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In general, for mentored CDAs, individuals are NOT eligible if they:

- have a pending application for:1) any other PHS career award that duplicates the provisions of the proposed NIH program; 2) an NIH institute-specific K22, or a Pathway to Independence Award (K99/R00); and/or

- have been or are currently a PD/PI on an independent NIH research grant (such as R01) or a subproject leader on a Program Project (P01) or Center Grant (P50), or a non-PHS equivalent to these grants.

Most independent (non-mentored) CDAs require that the applicant have independent, peer-reviewed support at the time the award is made. Some of the participating NIH ICs require the candidate to have an NIH research grant at the time of application and that the support be from their IC. Other NIH ICs will accept candidates with peer-reviewed, independent research support from other sources. Applicants must check the FOA for specific eligibility requirements.

# 12.4 APPLICATION REQUIREMENTS AND SUBMISSION DATES

## 12.4.1 Application

Before applying for a CDA, applicants should carefully review the guidelines in the FOA for the specific career award(s) of interest, noting especially the eligibility requirements, award provisions, requirements for a mentor, and review criteria. The participating ICs may have distinctive guidelines, requirements, and funding amounts for each FOA in order to accommodate the career needs of researchers working in fields related to their specific research missions. Candidates are therefore strongly encouraged to contact the staff person in the relevant IC listed in the FOA prior to preparing an application to discuss any specific provisions of the award.

All CDA applications have transitioned to electronic submission through Grants.gov. The specific FOA provides links to the application forms package as well as the appropriate application instruction guide. As with all NIH programs using electronic submission, a CDA application uses a combination of SF424(R&R) and PHS398 forms. A separate section (Section I.7) of the SF424(R&R) Application Guide is included that provides supplemental instructions for preparing a CDA application. Further assistance is available from GrantsInfo.

Applications must contain Candidate Information, Statements of Support, Environment and Institutional Commitment to the Candidate, as well as a Research Plan. The Candidate Information section includes required information about the candidate and must justify the need for the requested period of support, be tailored to the prior research experience and career development needs of the candidate, and for mentored CDAs be designed to move the candidate from a mentored phase to an independent status. The research plan must have intrinsic research importance as well as serve as a suitable vehicle for learning the methodology, theories, and skills necessary for a well-trained independent researcher. For mentored award programs, the research plan must also include a description of the relationship between the mentor's research and the candidate's proposed research plan

Other than the K22 application from an unaffiliated candidate, all applications require documents describing the Environmental and Institutional commitment to the candidate.

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For mentored award programs the career development application also must include Statement by Mentor(s), Co-Mentor(s), Consultant(s) and Contributor(s) as well as a statement describing the institution's commitment to the candidate's development.

#### 12.4.1.1 Letters of Reference

At least three (but no more than five) letters of reference are required for all new and resubmission mentored CDA applications. The letters should be from individuals not directly involved in the application, but who are familiar with the candidate's qualifications, training, and interests and include advisory committee members (if applicable). However, the candidate's mentor(s) of the application must not submit a separate letter of reference because a mentor's statement is required as part of the application. The letters of reference should address the candidate's competence and potential to develop into an independent biomedical, behavioral, or clinical investigator.

Electronic submission of CDA applications requires electronic submission of reference letters as well. However, reference letters are submitted directly by the referee through the eRA Commons and not as part of the electronic application that goes through Grants.gov. Reference letters will be joined with the electronic application within the eRA system once an application completes the submission process. Applications that are missing the required letters may be delayed in the review process or not accepted at all. Complete instructions for candidates and referees are found in Part I, Section 7.3 of the SF424(R&R) Application Guide for Adobe Applications.

#### 12.4.1.2 Concurrent Applications

NIH will not accept any application in response to an FOA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial resubmission of an application already reviewed, but such applications must include an Introduction addressing the previous critique.

#### 12.4.1.3 Environment and Institutional Commitment to the Candidate

The applicant organization must define and document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with staff capable of productive collaboration with the candidate. The institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of the award. The institution should indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in the application. The applicant should describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

The institution should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development. The document should include the institution's agreement to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured research career development experience. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award.

Because of the diverse types of CDAs, applicants should contact the appropriate awarding IC scientific/research contact named in the specific FOA to determine the level of commitment required for

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the application. Institutional commitment to the candidate may not be contingent upon the receipt of the CDA.

***Off-Site Training Experience.*** A candidate may propose a career award experience that involves sites beyond the applicant organization, provided that the goals of the total experience are encompassed and supported under the appointment with the applicant organization.

### 12.4.1.4 Training in the Responsible Conduct of Research

All CDA applicants (mentored and non-mentored) must include a description of the formal and informal activities related to instruction in the responsible conduct of research planned for the proposed research program. Specifically, applicants must include a description of a plan for instruction in responsible conduct of research. This description should document prior instruction in or the nature of the applicant's participation in responsible conduct of research instruction (lecturer, discussion leader, etc.) during the applicant's current career stage (including the date of last occurrence) and propose plans to participate in instruction in responsible conduct of research. Such plans must address four instructional components, format, subject matter, duration of participation, and frequency of participation, as outlined below. Applications lacking a plan for participation or instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process.

1. ***Format.*** Substantial face-to-face discussions among the career recipient/scholars, other individuals in a similar training status, and mentors along with a combination of didactic and small-group discussions (e.g. case studies) are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs (see below), or unusual and well-justified circumstances.

2. ***Subject Matter.*** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

a) conflict of interest – personal, professional, and financial

b) policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices

c) mentor/mentee responsibilities and relationships

d) collaborative research including collaborations with industry

e) peer review

f) data acquisition and laboratory tools; management, sharing and ownership

g) research misconduct and policies for handling misconduct

h) responsible authorship and publication

i) the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all aspects of responsible research conduct.

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3. ***Faculty Participation.*** Mentors and other appropriate faculty are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. For institutional Career Awards, training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.

4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the career recipient/scholars, mentors and other appropriate faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. Individuals at the early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in responsible conduct of research at least once during this career stage. Non-mentored career award recipients may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the career award recipient/scholar is not actually supported by an NIH grant. This instruction must be documented in the submitted plan.

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### 12.4.1.5 Budget

CDAs provide limited costs, generally covering only applicable salary and fringe benefits for the candidates, as well as a fixed amount for research development support. Costs requested and awarded for CDA programs must be consistent with applicable Federal cost principles. Salary amounts as well as the research development costs can vary by CDA program and then within a particular program even by each participating NIH IC. Applicants are advised to consult the relevant FOA for guidelines on allowable costs and budget limitations.

The transition to electronic submission included a change in business process with respect to budget information. Detailed budget information is now required as part of the initial application; however it is limited to the senior/key person information for only the candidate and then the total amount of requested research development support in budget section F.1. Other Direct Costs/Materials and Supplies. A budget justification is also required and should be used to provide a detailed description for the specific research development support costs. Instructions are provided in the applicable Application Guide and specific FOAs.

As with all NIH training programs, Facilities and Administrative costs for CDAs are provided at a rate of 8% of modified total direct costs.

### 12.4.1.6 Submission Dates

For all parent CDA FOAs, NIH receives applications three times each year using standard submission dates. For a list of the standard submission dates and review cycle, see

http://grants.nih.gov/grants/funding/submissionschedule.htm. IC-specific FOAs may use special submission dates instead of the standards dates, but the FOA will clearly indicate if standard or special submission dates are used.

## 12.5 REVIEW

All CDA applications will undergo peer review as noted in The Peer Review Process in Part I; however, the actual review criteria and other review considerations are different as described herein.

### 12.5.1 Overall Impact

Reviewers should provide their assessment of the likelihood for the candidate to maintain a strong research program, taking into consideration the criteria below in determining the overall impact/priority score.

### 12.5.2 Scored Review Criteria

For CDA applications, reviewers will consider each of the five review criteria below in the determination of the scientific and technical merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have a major scientific impact.

- Candidate
- Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
- Research Plan
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s); and for non-Mentors the Mentoring Plan
- Environment and Institutional Commitment to the Candidate

These criteria are listed in logical order and not in order of priority. Since the specifics for each of these criteria can vary for the various CDA programs, the review criteria are described in detail in the FOA. Note that different ICs may employ additional review criteria.

### 12.5.3 Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

- ***Protection of Human Subjects.*** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

  For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate: 1) the

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justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

- ***Inclusion of Women, Minorities and Children.*** When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

- ***Vertebrate Animals.*** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

- ***Biohazards.*** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

- ***Resubmission Applications.*** The committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

- ***Renewal Applications.*** The committee will consider the progress made in the last funding period.

- ***Revision Applications.*** Rare for CDAs; however, when reviewed the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional information for these review criteria may be provided in specific FOAs.

### 12.5.4 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

- ***Training in the Responsible Conduct of Research.*** Reviewers will evaluate plans for providing instruction in responsible conduct of research as well as the past record of instruction, where applicable. Reviewers will specifically address the four Instructional Components (Format, Subject Matter, Duration and Frequency of instruction) as detailed above. Plans and past record will be rated as **acceptable** or **unacceptable** and the summary statement will provide the consensus rating of the review committee. Applications with **unacceptable** plans will not be funded until the applicant provides an acceptable, revised plan.

- ***Select Agents.*** Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor

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possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

- ***Resource Sharing Plans.*** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

- ***Budget and Period of Support.*** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Candidates should carefully review the applicable FOA for complete information associated with the peer review process. The FOA may describe additional information to be submitted for each of the above elements.

## 12.6 NOTIFICATION OF ACTION

Shortly after the initial peer review meeting, candidates receive an e-mail indicating that the SRG recommendation/priority score is available in the eRA Commons. The candidate is also notified via an e-mail when the summary statement (written critique) is available in the eRA Commons.

The PO may notify the applicant about the final review recommendation. The applicant should direct any questions about initial review recommendations and funding possibilities to the designated IC PO, not the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons. If the application is under consideration for funding, NIH will request additional information. After all program and administrative issues have been resolved, the NoA will be issued for those applications selected for funding.

## 12.7 PERIOD OF SUPPORT

The NIH awarding IC will notify the individual of the intention to make an award and confirm the plans for the start of support. An award is for a period of 3 to 5 years and provides support for salary and research-development support costs. Support beyond the first year shall be based on an assessment by NIH staff of the effectiveness of the development opportunity and continued opportunity for growth, as reflected in the grantee's annual progress report. Continuation of awards is contingent upon future Federal appropriations.

Mentored CDAs are not renewable. Non-mentored CDAs may be renewable; awards may be competitively renewed at the discretion of the participating NIH ICs. Only a few of the NIH ICs permit competitive renewals.

Note the period of support for the K99/R00 program is awarded in 2 distinct phases. Phase I covers only the K99 period; phase II is the R00 portion and is contingent upon meeting certain criteria, including the submission and acceptance of a R00 application by the NIH IC.

Some K22 programs also have 2 distinct funding phases where specific criteria must be met before funding is provided for the second phase.

Note, the K99/R00 and some K22 programs allow NIH intramural scientist to apply. For those selected for funding, the period of support on any award issued will only reflect the period funded by NIH

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extramural funds. Any period of support supported by NIH intramural funds will not be evident in the NoA.

## 12.8 ALLOWABLE AND UNALLOWABLE COSTS

Policies included in the applicable cost principles and the NIHGPS govern the expenditure of all CDA funds, unless otherwise indicated in the NoA.

### 12.8.1 Salaries and Fringe Benefits

Requested salary and fringe benefit amounts must be in accordance with institutional policies applied consistently to individuals in like circumstances and must be supported by acceptable accounting principles. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure. Salary amounts requested on CDA grants must be based on the investigator's IBS prorated for their commitment on the project. While requested salary and fringe benefit information is provided in the initial application, confirmation of these costs may be required prior to the issuance of an award.

The amount funded as salary for a CDA is not uniform throughout the NIH participating ICs. Salary limits vary by IC and are noted in the FOA. Note the limit is on salary only; applicable fringe benefits are provided in addition to the salary. The candidate is strongly advised to contact the relevant awarding IC for any distinct guidelines, requirements, and allowable funds. Salary costs charged cannot exceed the applicable legislative salary cap (http://grants.nih.gov/grants/policy/salcap_summary.htm).

The grantee institution may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale. Salary supplementation is allowable, but must be from non-Federal sources unless explicitly authorized by the Federal program from which such funds are derived. In no case may PHS funds be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the CDA.

NIH IC limitations on awarded salary levels do not limit the grantee's rebudgeting authority. Institutions may rebudget the total costs awarded to cover additional salary charges, provided they are within the approved scope of the project and consistent with the institution's salary scale as long as the cost charged is within the applicable legislative salary cap.

Salary support for ancillary personnel (e.g. administrative assistance or secretarial support) on CDAs is not allowable.

Salary support for mentors is not allowable on individual mentored CDAs.

Salary support for research technicians or study coordinators for clinical studies are generally allowable but are budgeted as part of the Research Development Support Costs described below.

### 12.8.2 Research Development Support Costs

CDAs may include a fixed amount for research development support costs. This amount may vary by IC and is commonly used for supplies, equipment, technical personnel, travel to research meetings or training, tuition/fees for courses and computational services.

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### 12.8.3 Proposal Preparation Costs

Mentored CDA programs provide support with a goal of leading to research independence for an individual. Since research independence is achieved through applying for other research support, consistent with these objectives, it is allowable for effort devoted to proposal preparation costs for subsequent research support to be charged to a mentored CDA award. This can be considered part of the awarded effort commitment of the mentored CDA or an increase to that commitment with the allowable salary provided as applicable.

### 12.8.4 Facilities and Administrative Costs

For career awards other than the R00 phase of the K99/R00 and other than State, local, or Indian tribal governments, grantees will receive F&A costs at 8 percent of modified total direct costs. 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.

## 12.9 REBUDGETING OF FUNDS

Funds awarded on CDAs may typically be rebudgeted within direct cost categories without prior approval; however restrictions on rebudgeting may be noted in the NoA.

Rebudgeting of salary funds in an NIH-supported research grant for the salaries or fringe benefits of individuals which are freed as a result of a career award, may not be rebudgeted without the prior approval of the NIH awarding IC.

## 12.10 CARRYOVER AUTHORITY

Unless otherwise noted by a specific term of award, Individual CDAs have automatic carryover authority. However, for most Institutional CDAs, carryover requires prior approval. The NoA will specify whether or not the grantee must obtain prior approval to carry over funds.

For the two-phased K99/R00 program, automatic carryover from the K99 phase to the R00 phase is allowed. The K99 grantee should include a note on the FSR regarding the carryover to the R00 phase.

## 12.11 REPORTING REQUIREMENTS

Failure to comply with reporting requirements and to submit the required forms in a timely manner may result in an expenditure disallowance or a delay in any continuation funding.

### 12.11.1 Progress Reports

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 Web site at http://grants.nih.gov/grants/forms.htm. Most individual CDA awards (mentored and non-mentored) are awarded under SNAP authorities and are therefore must be submitted electronically using the eSNAP feature in the eRA Commons. In addition to the general SNAP progress report instructions found in the PHS 2590, CDA recipients are instructed to review Section 5 of the PHS 2590, Additional Instructions for Preparing Continuation Career Development Award (CDA) Progress Reports. Incomplete or inadequate progress reports may be returned for revision and may result in a delay of continued support.

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Following completion or termination of a project period, the grantee must submit a final progress report to the NIH awarding IC within 90 days after the end of grant support as part of the Closeout documents described below.

### 12.11.2 Federal Financial Report

For individual CDAs awarded under the SNAP authorities, an annual electronic FFR is not required. Only a final FFR is required at the end of the project period (see Administrative Requirements—Monitoring—Reporting—Financial Reports and Administrative Requirements—Closeout—Final Reports in IIA).

### 12.11.3 Closeout

The Closeout requirements included in IIA (see Administrative Requirements—Closeout—Final Reports) apply to all Individual CDAs (mentored and non-mentored). For Institutional Scientist Development Programs the closeout requirements apply with the exception of the Final Invention Statement; invention reporting is not applicable to K12s & KL2s thus a final invention statement is not required as part of the closeout process.

### 12.11.4 Post Closeout Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of CDA programs. Accordingly, CDA awardees may be contacted after the completion of any CDA award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

## 12.12 CHANGES IN THE PROJECT

The approval of the NIH awarding IC is required for a transfer of the CDA to another institution, or a project change. Note, individual mentored and non-mentored CDAs may not be transferred to another PD/PI.

The Change of Grantee Organization policies described in IIA apply to Individual CDAs as long as the transfer is between domestic institutions. For mentored CDAs, the recipient must have a mentor at the new institution. If the transfer also involves a change in mentor, supporting documentation from the new mentor will be required. Consultation with the applicable NIH program staff and/or grants management staff is strongly encouraged when a change of institution is being considered.

CDAs are awarded under the NIH Standard Terms of Award and as such grantees have the authority to extend the final budget period of a project period without additional funds for up to 12 months. Grantees are reminded that all terms and conditions and programmatic requirements apply during the extension period. For instance, the full-time appointment and minimum effort requirements must continue for the entire extension period. Grantees should be mindful of these requirements when deciding how much additional time is needed.

### 12.12.1 Temporary Off-Site Training Experience

A temporary career development experience at another institution, including a foreign laboratory, may be permitted if the proposed experience is directly related to the overall goals and purpose of the K award. Only local institutional approval is required if such an arrangement does not exceed 3 months. For longer periods (not to exceed 12 months), prior written approval from the NIH awarding IC is required. The

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written request must document the approval of the grantee organization and the adequacy of arrangements for off-site training. Support from the career award will continue during such an off-site experience. For some CDAs additional information is required as part of any prior approval request:

- For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of each of these awards, a request for approval of an off-site training experience lasting more than 3 months must address the impact of such action on the awardee's ability to make sufficient progress to meet the goals of the award. For example, for a K99 phase awardee, the request must describe how the off-site experience will affect the awardee's ability to transition to the R00 phase.

- For K05, K07 leadership, and K24 awardees, the request must include a letter assuring that arrangements have been made to continue to commit the appropriate effort to the research and to provide mentoring.

- For K12 and KL2 Scholar appointees, because of the short duration of the mentored phase of each of these awards, a request for approval of an off-site training experience lasting more than 3 months must address the impact of such action on the scholar's ability to make sufficient progress to meet the goals of the program.

## 12.13 OTHER TERMS AND CONDITIONS

Except as otherwise noted below, the provisions of IIA apply to all CDA programs. This includes all Public Policy Requirements, Objectives, and Other Appropriation Mandates such as civil rights; the protection of human subjects, including data and safety monitoring requirements; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant DNA and human gene transfer research. See Subpart IIA for a complete list of applicable requirements.

In addition, all Administrative Requirements described in IIA also apply to CDA program unless an exception is noted below. These include requirements such as prior approvals; availability of research results, publications, NIH Public Access policy, invention reporting, and program income. See IIA for a complete list of applicable administrative requirements.

### 12.13.1 Leave

Since CDA awardees are employees of the institution, applicable institutional leave policies for leave such as vacation, sick, parental, etc. apply to individuals supported by NIH CDAs.

CDAs are expected to be for continuous support of an individual; however, in certain circumstances, candidates will be permitted to take a leave of absence. Circumstances include personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. A leave of absence or sabbatical greater than three months must be requested and approved in writing by the NIH awarding IC. A leave of absence less than 3 months only requires institutional prior approval.

For some CDAs additional information is required as part of any prior approval request:

- For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of each of these awards, a request for approval of a leave of absence lasting more than 3 months must address the impact of such action on the awardee's ability to make sufficient

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progress to meet the goals of the award. For example, a K99 phase awardee must describe how the leave will affect the awardee's ability to transition to the R00 phase.

- For K05, K07 leadership, and K24 awardees, the request for a leave of absence lasting more than 3 months must include a letter assuring that arrangements have been made to continue to commit the appropriate effort to the research and to provide mentoring.

- For K12 and KL2 Scholar appointees, because of the short duration of the mentored phase of each of these awards, a request for a leave of absence lasting more than 3 months must address the impact of such action on the scholar's ability to make sufficient progress to meet the goals of the program.

#### 12.13.1.1 Unpaid Leave

Leave without award support may not exceed 12 months. Such leave requires prior written approval of the awarding component and will be granted only with justification. When approved, the K award will be placed in a no-cost extension for the duration of the unpaid leave and no charges to the grant will be allowed during that period, although continued coverage of health insurance would be allowable if in accordance with institutional policy. Such leave does not reduce the total number of months of program support for which an individual is eligible.

### 12.13.2 Statement of Appointment—Institutional CDAs Only

At the time of the initial appointment of K12 or KL2 scholars, the Program Director may submit a Statement of Appointment (Form PHS 2271) for each scholar to the NIH awarding IC to document the appointment of scholars to institutional CDAs. This policy varies with ICs. Contact the CGMO of the awarding IC to confirm their policy on submitting a PHS 2271. When 2271s are required, this information must be submitted using the xTrain feature in the eRA Commons.

### 12.13.3 Early Termination

Consultation with the applicable NIH program staff and/or grants management staff is strongly encouraged when a termination is being considered before the scheduled project end date. When an institution plans to terminate an award, the awarding IC must be notified in writing at the earliest possible time, so that appropriate instructions can be given for termination. NIH will issue a revised NoA to specify the changed period of support.

NIH may terminate a CDA before its normal 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 recipient in writing of the determination, the reasons for the determination, the effective date, and the right to appeal the decision.

The NIH awarding IC should be notified immediately if a sponsoring institution wants to terminate a K12 scholar, or if the scholar decides to terminate the appointment before the scheduled expiration date.

### 12.13.4 Other Income: Generation and Disposition of Professional Fees

CDA awardees may retain royalties and fees from activities such as scholarly writing, service on an advisory group, honoraria from other institutions for lectures or seminars, fees resulting from clinical practice, professional consultation, or other comparable activities, provided these activities remain

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incidental, are not required by the research and research-related activities of the CDA, and provided that the retention of such pay is consistent with the policies and practices of the grantee institution. No other income or fees may be retained by the CDA recipient and must be assigned to the grantee institution for disposition by any of the following methods:

- The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the grantee institution.

- The funds may be used for health-related research purposes.

- The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services and forwarded to the Director, Office of Financial Management, NIH, Bethesda, MD 20892. Checks must identify the relevant award account and reason for payment.

Adequate records regarding the source, receipt and disposition of fees and other income are to be maintained by the institution for the time period(s) specified in 45 CFR part 74.53.

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# 13 MODULAR APPLICATIONS AND AWARDS

## 13.1 GENERAL

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

## 13.2 APPLICABILITY

Modular procedures are required to be used for new, renewal, and resubmission applications as well as for revisions for individual research project grants (R01), small grants (R03), exploratory/development grants (R21), Clinical Trial Planning Grants (R34) and Academic Research Enhancement Awards (R15) that request up to a total of $250,000 of direct costs per year (excluding consortium F&A costs), regardless of whether the application is an investigator-initiated application or is one submitted in response to a PA/RFA. Modular procedures do not apply to SBIR and STTR Phase I grants (R43 and R41), and do not apply to foreign (non-U.S.) organizations.

Instructions for specific grant mechanisms other than the R01 and guidelines for IC programs may indicate a particular number or range of modules allowed.

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

## 13.3 APPLICATION REQUIREMENTS

Modular applications must be submitted on the SF424 (R&R) forms. Paper-based applications that include modular budgets will no longer be accepted.

### 13.3.1 Budget

Modular applications request direct cost funding in modules of $25,000, for up to $250,000 each year for covered activity codes.. F&A costs for subcontracts are not included in determining the direct cost modular amount or the total cost amount requested. The modules should be a reasonable estimate of allowable, allocable, and reasonable costs for the proposed project. In addition, F&A costs at the negotiated rate for the applicant institution are also allowable.

Since only limited budget information is required for submission of a modular application, the PHS 398 Modular Budget Component, which is included as part of the electronic SF424 (R&R) form set, must be submitted to NIH through Grants.gov. Sample modular application budget pages are available at http://grants.nih.gov/grants/funding/modular/modular.htm. The standard SF 424 Research and Related Budget Component is not used for application using modular budgets.

The PHS 398 Modular Budget Component includes information on direct costs modules as well as F&A costs; budget justifications for all personnel by position, role, and level of effort (measured in person months); consultants; and 'to be appointed' positions. No individual salary information should be provided. Applicants must use the applicable NIH salary cap when determining the number of modules to request (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages in IIA). Given the authority to rebudget and carry forward unobligated balances, funds

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generally should be available to cover modest increases in any statutorily imposed salary cap. NIH also limits the compensation for graduate students. Compensation includes salary or wages, fringe benefits, and tuition remission. These limits should be used when estimating the number of modules. See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages in IIA for more information on compensation of graduate students.

When applicable, a separate budget justification must address consortium/contractual costs (including applicable F&A costs) rounded to the nearest $1,000. The narrative should list the individuals and organizations with whom consortium or contractual arrangements have been (or will be) made, the level of effort of senior/key personnel (measured in person months) and their role on the project, and indicate whether the collaborating organization is foreign or domestic.

A typical modular application will request the same number of modules for each year. However, well-justified modular increments (up to the $250,000 modular ceiling) or decrements in the total direct costs for any year of the project that reflect substantial changes in expected future activities may be requested at the outset. For example, a major equipment purchase in the first year may justify a higher overall budget in that year, but not necessarily in succeeding years. There is no provision for escalation in future years. NIH requires additional narrative budget justification if there is a variation in the number of modules requested from year to year.

## 13.4 APPLICATION REVIEW AND AWARD

SRGs evaluate the budget on the basis of a general, expert estimate of the total effort and resources required to carry out the proposed research. If the SRG recommends an adjustment in the project budget, the recommended adjustment will be in terms of an entire module.

Following peer review, for applications being considered for award, the IC will request information about "Other Support" and, as applicable, the use of human or 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. An IC may need to reduce the award amount to accommodate the IC's cost management plan.

The award budget will be a noncategorical budget specifying approved total direct costs and F&A costs, if applicable.

## 13.5 POST-AWARD ADMINISTRATION

Grantees have discretion in determining how to allocate and account for costs related to modular awards within their organizational accounting system. However, institutions are still required to ensure that all costs charged to modular awards are in accordance with applicable costs principles, the NIH GPS, and any legislatively imposed restrictions.

Modular awards are subject to the standard NIH Terms of Award and are awarded under the SNAP authorities. However, since the award is issued without direct cost budget categories, the significant rebudgeting provision described as a potential change of scope indicator does not apply to modular grants.

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Grantees may submit requests for administrative supplements to the CGMO of the NIH awarding IC, but must provide a detailed (non-modular) budget.

Competing Revisions should be submitted to the NIH using the modular budget component.

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# 14 SUPPORT OF SCIENTIFIC MEETINGS (CONFERENCE GRANTS)

## 14.1 GENERAL

NIH supports scientific meetings, conferences, and workshops (hereafter "conferences") that are relevant to its scientific mission and to public health under the R13 and U13 activity codes. NIH's support of conferences is contingent on the interests and priorities of the individual ICs. Most ICs provide conference support although their budget guidelines may vary. Prior approval (advance permission) is required before submission of an application for conference support. Advance permission to submit an application must be requested early in the process and no later than 6 weeks before the application submission date. Permission to submit a conference grant application does not assure funding or funding at the level requested. The letter from the NIH IC conference grant contact person (http://grants.nih.gov/grants/guide/contacts/parent_R13_U13.html) documenting advance permission to submit an application must be included as part of the PHS 398 Cover Letter component of the application. Potential applicants must contact the funding IC before submission for specific information as well as to ensure compliance with submission requirements. Applications for conference support must be submitted based on the published receipt dates. In general, NIH will not issue a conference grant award unless it can be issued before the conference start date. Awarding a conference grant after a conference has been held should only be done when an IC can determine or document that funding of post-conference activities is consistent with the approved application.

## 14.2 APPLICABILITY

This chapter applies to grants that support domestic and international conferences. If a policy is not addressed in this chapter, then IIA coverage applies.

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

## 14.3 DEFINITIONS

***Scientific Meeting (Conference).*** A gathering, symposium, seminar, workshop, or any other organized, formal event where people assemble to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge.

***International Conference.*** A scientific meeting so designated by its sponsor or one to which open invitations are issued on an equal basis to potential participants in two or more countries other than the United States or Canada. The meeting may be held in the United States or any country, subject to U.S. Department of State travel restrictions.

***Domestic Conference.*** A scientific meeting held in the United States or Canada primarily for U.S. or U.S.-Canadian participation (even if foreign speakers are invited).

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## 14.4 ELIGIBILITY

Domestic institutions or organizations, including established scientific or professional societies, are eligible to apply for conference support. Both domestic and international conferences may be supported; however, an international conference may be supported only through the U.S. representative organization of an established international scientific or professional society. An individual is not eligible to receive a grant in support of a conference.

## 14.5 APPLICATION REQUIREMENTS

Conference grant applications are electronically submitted using an application package that combines SF424 (R&R) and PHS398 components. Applications packages and instructions are provided with each FOA. Applicants must complete and submit a detailed categorical budget using the Research & Related Budget component; however, no indirect (F&A) costs may be requested. The appropriate NIH IC Conference Grant Contact (http://grants.nih.gov/grants/guide/contacts/parent_R13_U13.html) should be consulted for guidance regarding any IC-specific budget and project duration requirements. Application requirements and further information on NIH support for conferences and scientific meetings (R13 and U13) may be found on the NIH Web site at http://grants.nih.gov/grants/funding/r13/ or in applicable FOAs.

## 14.6 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

In addition to any applicable public policy requirements and objectives specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA, the following apply to NIH Conference Grants.

### 14.6.1 The United States Hotel and Motel Fire Safety Act of 1990

The Hotel and Motel Fire Safety Act of 1990 (PL101-391) was passed into law by Congress to save lives and protect property by promoting fire and life safety in hotels, motels and other places of public accommodation. PL101-391 states that federally funded meetings and conferences cannot be held in properties that do not comply with the law. PL101-391 is applicable to all places of public accommodation, and requires that such properties are equipped with:

- hard-wired, single-station smoke detectors in each guestroom in accordance with the National Fire Protection Association (NFPA) standard 72;
- an automatic sprinkler system, with a sprinkler head in each guest room in compliance with NFPA standards 13 or 13R. Properties three stories or lower in height are exempt from the sprinkler requirement.

The United States Fire Administration (USFA) is charged with carrying out FEMA's responsibilities with respect to the Hotel and Motel Fire Safety Act of 1990. In addition to compiling, maintaining and publishing the National Master List, USFA is also responsible for taking steps to encourage states to promote the use of automatic sprinkler systems and automatic smoke detection systems.

### 14.6.2 Guideline on the Inclusion of Women

Conference grant applicants must comply with the *Guidelines on the Inclusion of Women, Minorities, and Persons with Disabilities in NIH Supported Conference Grants*

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(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.

## 14.7 APPLICATION REVIEW

Applications for conference grants will be reviewed for programmatic relevance and for merit as described in The Peer Review Process in Part I and applicable FOA.

## 14.8 FUNDING

Grants or cooperative agreements may be used to provide conference support. A cooperative agreement may be awarded if the NIH awarding IC determines that it needs to have substantial involvement in the planning and conduct of a conference.

Grant funds may not be used to provide general support for international conferences held in the United States or Canada. Grant funds may be awarded to support only specific aspects of such conferences. An example would be a selected symposium, panel, or workshop, including the costs of planning and travel of U.S. participants.

Awards in support of a single conference will be made for a project period commensurate with the time involved in planning and conducting the conference and post-conference follow-up, usually 1 year. A conference grant made to a permanently sponsoring organization for conferences held annually or biennially on a recurring topic may be awarded for up to a total of 5 years and will be funded annually, based on the availability of funds. Continued funding beyond the first year will be contingent on a report of satisfactory progress submitted in accordance with SNAP instructions. A change in conference focus requires NIH awarding IC prior approval.

## 14.9 ACKNOWLEDGMENT OF FUNDING SOURCE AND DISCLAIMER

When a conference is funded by an NIH grant or cooperative agreement, grantees must include the following statement on conference materials (including promotional materials, agenda, and internet sites):

> *"Funding for this conference was made possible (in part) by (Insert Grant/Cooperative Agreement #) from (insert name of NIH IC). The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the NIH; nor does mention by trade names, commercial practices, or organizations imply endorsement by the U.S. Government."*

Appropriate use of the NIH or HHS logo on conference materials is of particular importance. Neither logo should be displayed if it would cause confusion as to the source of the conference or give the false appearance of government endorsement. Accordingly, unless specifically authorized by the award, any use of the HHS and/or NIH logo requires prior approval. Unauthorized use of the HHS or NIH name or logo may result in imposition of civil monetary penalties (as provided in 42 CFR part 1003).

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# 14.10 ALLOWABLE AND UNALLOWABLE COSTS

The following highlights allowable and unallowable costs under conference grants. No costs other than those specified in this subsection as allowable, including any qualifications on their allowability, are permitted under conference grants.

## 14.10.1 Allowable Costs

***Conference Services.*** Grant funds may be used for necessary recording of proceedings, simultaneous translation, and subsequent transcriptions.

***Consultant Services.*** Grant funds may be used to pay consultant fees, including travel and supporting costs (per diem or, where applicable, subsistence).

***Equipment Rental.*** Grant funds may be used for the rental of necessary equipment.

***Federal Employees.*** See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter.

***Meals.*** When meals are justified by the applicant as an integral and necessary part of a conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, as qualified under Travel below.

***Publication Costs.*** When grant funds are awarded to pay for either the entire or partial cost of publication of proceedings or a book or pamphlet, allowable costs include special plates, charts, diagrams, printing, distribution, mailing, postage, and general handling, unless otherwise specified at the time the grant is awarded.

***Registration Fees.*** Grant funds may not be used for registration fees paid by the grantee to other organizations on behalf of attendees. Grant funds may be used to help defray registration costs for some select conference attendees (for example, women, racial/ethnic minorities, persons with disabilities, other individuals who have been traditionally underrepresented in science, graduate students).

***Salaries.*** In accordance with the policy of the 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.

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Proposed per diem or subsistence allowances must be reasonable and limited to the days of attendance at the conference plus the actual travel time to reach the conference location by the most direct route. Local mileage costs only may be paid for local participants. Where meals and/or lodgings are furnished without charge or at a nominal cost (e.g., as part of the registration fee), the proposed per diem or subsistence allowance must take this into consideration.

Transportation costs for attendees and participants at the conference may not exceed coach class fares. In all cases, U.S. flag carriers will be used where possible (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Travel in IIA).

### 14.10.2 Unallowable Costs

***A&R.*** Not allowable.

***Entertainment and Personal Expenses.*** Costs of amusement, diversion, social activities, ceremonials, and related incidental costs, such as bar charges, tips, personal telephone calls, and laundry charges of participants or guests, are unallowable. However, meals may be allowable as provided under Allowable Costs—Meals above.

***Equipment Purchase.*** Grant funds may not be used for the purchase of equipment.

***F&A Costs.*** Not allowable.

***Honoraria.*** Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or admiration may not be paid from grant funds.

***Local Participants' Expenses.*** With the exception of local mileage as indicated under Allowable Costs—Travel above, grant funds may not be used to pay per diem or expenses for local participants in the conference.

***Membership Dues.*** Not allowable.

***Research Patient Care.*** Not allowable.

***Visas and Passports.*** Not Allowable.

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## 14.11 ADMINISTRATIVE REQUIREMENTS

### 14.11.1 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 NoA and reported on the FFR (see Administrative Requirements—Reporting and Record Retention in this chapter).

Unless otherwise provided in the terms and conditions of the award, the 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 could seriously impact the degree to which any intellectual property rights could be protected.

## 14.11.2 Reporting and Record Retention

Upon completion or termination of a grant in support of a conference, grantees are responsible for submitting the final progress report and the final FFR in accordance with the Closeout provisions described in Administrative Requirements—Closeout in IIA. Submission details of the final FFR and Final Progress Report are described in respective subsections of Closeout.

### 14.11.2.1 Progress/Final Report

For single conferences, a final report of the conference must be submitted electronically through the eRA Commons, or by paper submission to the NIH DEAS Centralized Processing Center 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(s) of the person(s) shown on the application as the conference director or PD/PI(s)
- Name of the organization that conducted the conference
- A list of the individuals, and their organizational affiliations, who participated as speakers or discussants in the formally planned sessions of the meeting
- A summary of topics discussed/conclusions.

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 IC, copies of proceedings or publications resulting from the conference(s) may be substituted for the final report, provided that they contain the information specified for inclusion in the final report.

### 14.11.2.2 Federal Financial Report

Electronic submission through the eRA Commons of the final FFR 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 part 74.53 or 92.42 (see Administrative Requirements—Monitoring—Record Retention and Access in IIA).

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# 15 CONSORTIUM AGREEMENTS

## 15.1 GENERAL

This chapter 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, applicable reporting requirements, 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 IIA and the program income requirements of the award, also apply to consortium participant(s). Exceptions are noted in this chapter. The grantee is responsible for including the applicable requirements of the NIHGPS in its agreements with collaborating organizations (see Written Agreement in this chapter).

Under grants that include consortium agreements:

- The award will be made to a single grantee with a single PD/PI (or Contact PD/PI, in the case of multiple PD/PI applications), even though one or more organizations other than the grantee will carry out portions of the planned programmatic activity.

- The prime 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. This includes being able to provide appropriate oversight of all scientific, programmatic, financial, and administrative matters related to the grant.

Applicants are expected to detail their proposed collaborations as part of the grant application. If the application is approved as submitted, no further approval is required unless, during performance, the 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 in IIA). Applicants for STTR grants should follow the specific requirements for research collaboration established for that program (see Grants to For-Profit Organizations chapter).

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

- A list of all proposed performance sites, including those of the applicant organization and the consortium participant(s);

- A letter of commitment or intent signed by the applicant organization and the consortium participant(s); and

- Non-modular grant applications must include complete detailed budgets for each consortium participant. Modular grant applications must include an estimate of consortium total costs (direct costs plus F&A costs) each year as part of the budget narrative justification (see Modular Applications and Awards chapter).

The signature (or electronic equivalent) of the AOR/SO on the application signifies that the applicant organization and all proposed consortium participants understand and agree with the following statement:

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> "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.

## 15.2 ADMINISTRATIVE AND OTHER REQUIREMENTS

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

Note that most of these requirements only apply to a grantee's consortium relationships with subawardees. When the relationship is with a vendor that is providing routine goods and services within normal business operations that are ancillary to the operation of the research program, the public policy requirements listed below do not apply. The vendor must also be providing similar goods and services to many different purchasers and provide them in a competitive environment.

### 15.2.1 Written Agreement

The 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 an efficient collaborative venture. At a minimum, this agreement must include the following:

- Identification of the Project Director or Principal Investigator and individuals responsible for the research activity at each consortium participant along with their roles and responsibilities

- When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but need not be employees. Any consortium agreement must address the unique aspects to these individuals holding the PD/PI role.

- Procedures for directing and monitoring the research effort

- Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, procedures for review and approval of expenditures of grant funds at each organization and timing of applicable reporting requirements

- 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)

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- Procedures for identifying, handling and reporting financial conflicts of interest for all individuals involved in the design, conduct and reporting of the research in accordance with applicable regulations

- 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 in IIA), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the 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

- Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA).

## 15.2.2 Public Policy Requirements and Objectives

The 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, Objectives, and Other Appropriation Mandates in IIA 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 (see *Guidance on Engagement of Institutions in Human Subjects Research* http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html), and for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget in IIA). The list of organizations with approved assurances is available at the OHRP Web site: http://www.hhs.gov/ohrp/.

The animal welfare requirements that apply to grantees also apply to consortium participants and subprojects. The primary grantee is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. The approval of more than one IACUC is not required if the grantee and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted. If the prime grantee does not have an Assurance and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an Inter-institutional Assurance from OLAW. Under the Inter-institutional Assurance, the grantee and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance. The grantee is further responsible for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements in IIA). The list of organizations with approved assurances is

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available at the OLAW Web site (domestic institutions: http://grants.nih.gov/grants/olaw/assurance/300index.htm, and foreign institutions: http://grants.nih.gov/grants/olaw/assurance/500index.htm).

## 15.2.3 Allowable and Unallowable Costs

The grantee must include in consortium agreements the applicable government-wide cost principles and NIH cost policies described in the Cost Considerations chapter in IIA and, as appropriate, requirements related to allowable and unallowable costs in other sections of IIB. For example, a university 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.

## 15.2.4 Approval Authorities

The grantee is responsible for obtaining NIH awarding IC 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 IC prior approval is required.

## 15.2.5 Tangible Personal Property

### 15.2.5.1 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 in IIA).

### 15.2.5.2 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.

## 15.2.6 Audit

The grantee must require consortium participants to comply with the requirements of OMB Circular A-133 or 45 CFR part 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

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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 part 74.26(d).

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

## 16.1 GENERAL

Most of the policies contained in IIA apply to NIH grants made to foreign 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 AOR should contact the GMO. Specific exceptions and modifications of IIA requirements for foreign grants, and highlights of other policies, are set forth in this chapter. This chapter also includes policies that apply to domestic grants with a foreign component.

## 16.2 ELIGIBILITY

In general, foreign institutions and international organizations, including public or private non-profit or for-profit organizations, are eligible to apply for research project grants, but are not eligible to submit a modular grant application. 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 activity codes, such as program project grants (P01), may support projects awarded to a domestic institution with a foreign component. For purposes of this policy, a foreign component is defined as performance of any significant element or segment of the project outside the United States either by the 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 at a foreign site.
- 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) chapter for NIH policy on support of international conferences.

Grants may not be made to individuals in a foreign location (i.e., outside of the United States and its territorial possessions). Occasionally, a Kirschstein-NRSA individual fellowship award is made to a U.S. citizen or a non-citizen national to study in a foreign 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.) See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships for additional information.

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## 16.3 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.

Note, these additional criteria are not applied to applications from domestic institutions with foreign components or applications in response to an FOA requesting applications from foreign institutions only.

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

## 16.4 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

A complete listing of public policy requirements and objectives and their applicability to foreign grants is included in Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA. Several of the public policy requirements and objectives are highlighted below:

- ***Research Misconduct.*** The research misconduct requirements included in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Research Misconduct apply to foreign grants.

- ***Animal Welfare.*** The animal welfare requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Animal Welfare apply to foreign grants, regardless of the requirements of the home country.

- ***Human Subjects.*** The human subjects requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Human Subjects Protections, including the requirement for an assurance pursuant to 45 CFR part 46, apply to foreign grants and foreign consortium participants under domestic or foreign grants.

- ***Financial Conflict of Interest.*** The financial conflict of interest requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates— Financial Conflict of Interest apply to foreign grants.

- ***Inclusiveness in Research Design.*** Foreign grants are subject to the requirements for inclusion of women, members of minority groups, and children in research design as specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Inclusion of Children as Subjects in Clinical Research and Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender and Racial Ethnic Participation.

- ***Civil Rights.*** The civil rights requirements specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Civil Rights do not apply to foreign grants.

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- ***Lobbying.*** The requirements of Public Policy Requirements, Objectives, and Other Appropriation Mandates—Lobbying Prohibition, including disclosure reporting, apply to foreign grants.

- ***Debt.*** Foreign applicants are required to provide a certification of nondelinquency on debts owed to the United States as specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Nondelinquency on Federal Debt.

- ***Debarment and Suspension.*** Applicants/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 2 CFR part 376. All other foreign institutions and international organizations are subject to these requirements. See Public Policy Requirements, Objectives, and Other Appropriation Mandates—Debarment and Suspension for additional information on this requirement.

- ***Drug-Free Workplace.*** Foreign applicants and grantees may be exempted from the drug-free workplace requirements of 2 CFR part 182 based on a documented finding by the NIH awarding IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government. See Public Policy Requirements, Objectives, and Other Appropriation Mandates—Drug-Free Workplace for additional information on this requirement.

## 16.5 FUNDING AND PAYMENT

The application budget, requests for funds, and financial reports (see Reporting and Record Retention in this chapter) must be stated in U.S. dollars. 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. In special circumstances, foreign grantees may be eligible to receive funds by electronic deposit or wire transfer. 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. Grantees are required to maintain grant funds in an interest bearing account; however, interest earned in excess of $250 per year in the aggregate on advances of Federal funds must be returned in U.S. dollars by reimbursement check to OFM, and reflected on the annual FSR.

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

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# 16.6 ALLOWABLE AND UNALLOWABLE COSTS

The cost principles that apply to foreign organizations depend on the type of organization, i.e., for a university, OMB Circular A-21 would apply, with the following exceptions:

- ***Major A&R (>$500,000).*** Unallowable under foreign grants and domestic grants with foreign components.

- ***Minor A&R (<$500,000).*** Generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations. Minor A&R costs may be included and justified in any detailed budget of a competing application. Further, rebudgeting of active grants to accommodate minor A&R is also allowable; however, this does require NIH prior approval of the GMO. Additional information may be required (see Administrative Requirements—Alteration and Renovation Projects under Non-construction Grants in IIB).

- ***Customs and Import Duties.*** Unallowable under foreign grants and domestic grants with foreign components. This includes consular and visa 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 only equipment) to foreign institutions and international organizations to support the costs of compliance with NIH requirements. Some examples of NIH compliance requirements are the protection of human subjects (including the required education in the protection of human research participants), animal welfare, invention reporting, financial conflict of interest 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. These expenses should not be requested as a Direct Cost budget expense. Note the reference to "capital expenditures" for the purposes of allowable F&A costs do not include purchases of equipment. Equipment is still allowable as a direct cost. Since the F&A costs are intended for compliance costs only, other items normally considered an F&A cost can be requested as a direct cost, e.g. rent.

- ***Patient Care Costs.*** Patient care costs are provided only in exceptional circumstances.

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# 16.7 ADMINISTRATIVE REQUIREMENTS

## 16.7.1 Changes in Project and Budget

Foreign grants are subject to the NIH Standard Terms of award, see Administrative Requirements—NIH Standard Terms of Award in IIA. Inclusion in SNAP is at the discretion of the NIH awarding IC and will be specified in the NoA.

## 16.7.2 Change in Scope

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

### 16.7.3 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 IC and its National Advisory Council or Board. NIH awarding IC approval also is required for the transfer of a grant from a foreign organization to a domestic organization. Grantees adding or changing a foreign performance site within a funded grant award must obtain approval from the GMO before work can be performed at the added or changed foreign site.

### 16.7.4 Audit

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

### 16.7.5 Reporting and Record Retention

Foreign grantees must submit annual FFRs electronically through the eRA Commons, whether or not they are under SNAP. Foreign grantees are not paid through PMS and, therefore, do not submit cash transaction data to PMS. FFRs must be submitted in U.S. dollars and in English. The currency rate in effect at the time the FFR is prepared should be used in preparing the report. For the final FFR, NIH requires grantees to reimburse the U.S. government for funds not spent. Mail reimbursement checks in U.S. dollars to the OFM. The OFM will process the final FFR along with the final reimbursement check.

All foreign grantees, contractors, consortium participants, and/or subcontractors must comply with Bayh-Dole invention reporting requirements. Regarding intellectual property, foreign grantees have the same rights and obligations regarding invention ownership as U.S. grantees. (See http://www.iedison.gov and http://inventions.nih.gov.)

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

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# 17 GRANTS TO FEDERAL INSTITUTIONS AND PAYMENTS TO FEDERAL EMPLOYEES UNDER GRANTS

## 17.1 GENERAL

NIH may award grants to Federal entities. Although the activity under these grants will take place in a research environment, certain terms and conditions vary from those included in IIA due to the recipient's status as a Federal institution. This chapter specifies those differences as well as differences in treatment among different Federal institutions. This chapter does not apply to Federally Funded Research and Development Centers (also known as Government Owned Contract Operated facilities) since the grantee institution is the institution operating the facility. In addition, this chapter addresses the policies that apply to payments to (or on behalf of) Federal employees under grants, including grants awarded to organizations other than Federal institutions.

## 17.2 ELIGIBILITY

In general, Federal institutions are eligible to apply for NIH grants, including research project grants. Specific eligibility will be stated in each FOA. Federal institutions also must meet the eligibility requirements of the grant program from which support is sought. PHS organizational segments, other than IHS hospitals, may receive NIH grant support under exceptional circumstances only. Such circumstances may include situations where a project cannot be supported within the mission of the applicant PHS agency or organizational segment, the activity cannot be performed elsewhere, or its nonpursuit would have an adverse impact or potentially important effect on the NIH mission, and NIH determines a grant is the appropriate means of carrying out the activity. However, NIH may not award a grant to an NIH component.

Although the performance site may be at a level lower than the agency or department level of the Federal institution, when an award is made to an eligible Federal institution, the Federal agency or department will be the 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 AOR's signature on the face page of the application. The assurance requirement does not apply to VAMCs, Bureau of Prisons' (Department of Justice) hospitals, IHS hospitals, or other PHS organizational segments.

## 17.3 VA-UNIVERSITY AFFILIATIONS

Investigators with joint appointments at a VAMC (VA hospital) and an affiliated university must have a valid MOU that specifies (at both the university and the VAMC) the title of the investigator's appointment, distribution of compensation, the responsibilities of the proposed investigator, and the

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percentage of effort available for research at each institution. 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 AOR of the submitting university on an application to NIH that includes such an arrangement certifies that

- the individual whose salary is included in the application serves under a joint appointment documented in a formal MOU between the university and the VA, and
- there is no possibility of dual compensation for the same work or of an actual or apparent conflict of interest.

Under the above-described arrangement, there is no involvement of a VA-affiliated non-profit research corporation, which is eligible to apply for and receive NIH grants in its own right as a non-profit organization. The limitations on the payment of Federal salaries apply (see Allowable and Unallowable Costs in this chapter).

## 17.4 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

The requirements concerning disclosure of financial conflicts of interest (see Public Policy Requirements, Objectives, and Other Appropriation Mandates—Financial Conflict of Interest in IIA) do not apply to Federal employees and/or Federal agencies. All other Public Policy Requirements described in IIA apply to Federal grantees.

## 17.5 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 interagency agreements between agencies .

## 17.6 ALLOWABLE AND UNALLOWABLE COSTS

Allowable and unallowable costs under grants to Federal institutions will be determined by the established policies of the institution, consistently applied to both its own activities and to grant-supported activities, and the requirements of this subsection. In the absence of a governing organizational policy, the cost principles for State, local, and Indian tribal governments (OMB Circular A-87) will apply.

***Salaries.*** See Federal (U.S. Government) Employees below.

***Institutional Allowances Under Kirschstein-NRSA Individual Fellowships.*** Institutional allowances may be requested by Federal institutions sponsoring a predoctoral or postdoctoral fellow.

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***F&A Costs.*** F&A costs will not be provided to Federal institutions.

***Federal (U.S. Government) Employees.*** Whether or not costs will be charged to the grant, when a Federal employee will be involved in an NIH grant-supported activity in any capacity other than as an employee working on a grant to a Federal institution, or a study subject, 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 part 73, Subpart J for additional guidance.) The Federal employee should consult with their agency ethics officials to determine whether outside activity approval is required by their employing agency.

Only four types of costs—consultant fees, subject costs, salary or fringe benefits, and travel costs—can be charged to NIH grants on behalf of Federal employees, whether by a grantee or a consortium participant, and under the conditions specified only. Applicants/grantees should advise any Federal employee with whom these types of arrangements may be made to consult with their employing agency concerning their ability to participate and to meet the required conditions for payment. The applicant organization must submit, as part of the grant application, any letters or documentation specified below, and that documentation must be deemed acceptable by the GMO before the Federal employee's involvement in the project.

***Consultant Fees.*** Consultant fees are allowable only for medical personnel of the Uniformed Services of the United States (excluding PHS Commissioned Officers) and when all of the following conditions are present:

- The employees are providing the kind and extent of medical services approved in the grant award.
- Adequate numbers of qualified civilian personnel are not available to provide these services, and eligible Federal medical personnel are hired only in addition to those qualified civilian medical personnel, if any, who are available.
- The applicant organization provides prior written authorization from the proposed consultant's commanding officer that 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 federal employee is an outpatient or subject under study in connection with grant-supported activities.

***Salary or Fringe Benefits.*** In most circumstances no salary or fringe benefit payments may be made from NIH grant funds to support Federal employees. While the level of effort required for the research project must be allowed by the employing agency as part of the individuals' official duties, salary and fringe benefit costs associated with an individual participating in an official capacity as a career, career-conditional, or other Federal employees (civilian or uniformed services) are not allowable. Salary and fringe benefits payments may only be made when prior approval is obtained from an authorized official of the employee's agency and the employee is one of the following:

- A temporary employee specifically hired to assist in the performance of an NIH grant.
- A PHS Commissioned Officer or a civil service employee carrying out duties for which specific statutory authorization exists permitting direct Federal assistance in lieu of cash under the grant, or where the government is reimbursed for services rendered subject to restrictions

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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 IC;
  - total amount of salary paid from NIH grant funds is proportional to the time devoted to the project and does not exceed the total annual amount of pay and allowances the individual would have received if not in LWOP status; and
  - parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.
- A civil service employee participating in a grant to a non-Federal organization and all of the following conditions are met:
  - The individual is participating as part of an approved IPA assignment in a role other than as PD/PI. IPA assignments generally do not exceed 2 years and may not exceed 4 years of continuous duration (5 U.S.C. 3372). Based on this statutory time restriction, the involvement of the civil service employee should be limited in scope. Therefore, the proposed PD/PI for an NIH grant may not be participating through an IPA. On a case-by-case basis, the NIH awarding IC may determine that certain other senior/key personnel on the project are sufficiently critical to its long-term success that participation through an IPA is not appropriate. Note, a Federal agency may not send or receive on assignment an employee who has served under the mobility authority for 4 continuous years without at least a 12-month return to duty with the organization from which originally assigned (5 CFR part 334).
  - Before making any payment from NIH grant funds to such an employee, the 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.
- A part-time VA employee at VANPCs for which NIH grant funds are used to pay the differential between the individual's VA part-time salary and the salary level for a full-time VANPC commitment in proportion to the level of effort devoted to the project. Compensation must be in accordance with the established policies and salary structure of the VANPC and the total number of VA and VANPC hours should not exceed a full time position. Therefore, if the PD/PI has a part-time appointment with the VANPC, an appropriate portion of the individual's salary that would otherwise be supported by the non-profit VANPC may be charged to the NIH

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grant. The work paid for by the VANPC must not be for the same project paid for by VA time for VA salary in accordance with the VA policy set forth in the VHA Handbook 1200.17.

***Travel Costs.*** Travel costs are allowable if the employee is

- working under a grant to a Federal institution;
- performing allowable reimbursable services as specified under Salary or Fringe Benefits immediately above; or
- attending an NIH grant-supported conference
  - during non-duty hours,
  - while in a preexisting LWOP status or one that continues beyond the conference, or
  - while on detail to a State or local government, educational institution, or other non-profit organization.

Such payments must be made in accordance with established organizational policy and consistently applied regardless of the source of funds, and the parties concerned must take reasonable steps to ensure that there is no actual or apparent conflict of interest.

# 17.7 ADMINISTRATIVE REQUIREMENTS

## 17.7.1 Equipment Accountability

NIH will consider all nonexpendable personal property acquired under a grant awarded to a Federal institution as exempt (see 45 CFR part 74.33) for purposes of determining the accountability requirements of 45 CFR part 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 IC under the conditions specified in 45 CFR part 74.34.

## 17.7.2 Procurement Requirements

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

## 17.7.3 Intellectual Property

Inventions resulting from grants supporting the activities of Federal employees under grants to Federal institutions must be reported simultaneously to NIH and to the employing agency under the terms of EO 10096, as amended, and are subject to the government assignment of rights in invention of government employee requirements of 37CFR part 401. (See http://iEdison.gov for reporting requirements.) Any resulting patent applications and patents must identify the NIH award, consistent with the language of 37 CFR part 401.14(f)(4). In cases where the VA is involved with the invention but is not the grant recipient, and the recipient institution chooses not to elect title or pursue practical application of an invention, the recipient must note VA's involvement on its notice to NIH and provide a courtesy copy of the NIH notification to the appropriate VA office. NIH will notify the recipient and the VA whether NIH has an interest in taking title and/or continuing the pursuit of practical application of the invention.

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### 17.7.4 Reporting Requirements

Federal institutions must electronically submit annual FFRs regardless of whether the award is subject to SNAP. Since these grants are paid directly by OFM, NIH rather than through PMS; a quarterly cash transaction report is not submitted, thus is not available for NIH IC staff to use as an alternative for financial monitoring.

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# 18 GRANTS TO FOR-PROFIT ORGANIZATIONS

## 18.1 GENERAL

Some of the terms and conditions for grants to for-profit (commercial) organizations vary from the standard terms and conditions included in IIA. In addition, the terms and conditions of the SBIR and STTR programs vary from those otherwise applicable to for-profit organizations. This chapter addresses separately the policies applicable to for-profit organizations generally, and those that apply to SBIR and STTR awards specifically. It also highlights several policies in IIA that apply equally to for-profit and non-profit recipients. If an exception is not stated below or in the NoA, the terms and conditions specified in IIA apply, including requirements for the protection of human subjects and animal welfare.

## 18.2 ELIGIBILITY

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

## 18.3 ALLOWABLE AND UNALLOWABLE COSTS

### 18.3.1 Cost Principles

There are no cost principles specifically applicable to grants to for-profit organizations. Therefore, the cost principles for commercial organizations set forth in the FAR (48 CFR part 31.2) generally are used to determine allowable costs under NIH grants to for-profit organizations. As provided in those costs principles, allowable travel costs may not exceed those established by the FTR (available on-line at http://gsa.gov/portal/content/104790). The cost principles in 45 CFR part 74, Appendix E, are used to determine allowable costs under NIH grants to proprietary hospitals.

### 18.3.2 Independent Research and Development Costs

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

### 18.3.3 Facilities and Administrative Costs (Indirect Costs)

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

### 18.3.4 Profit or Fee

Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a 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.

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# 18.4 ADMINISTRATIVE REQUIREMENTS

For-profit organizations generally are subject to the same administrative requirements as non-profit organizations, including those relating to personal property title and management. Exceptions to or elaboration of those requirements for for-profit organizations are indicated below.

## 18.4.1 Equipment Accountability

For-profit grantees of NIH grants are nonexempt and subject to the requirements in 45 CFR part 74.34, as well as the conditions set forth in Administrative Requirements—Management Systems and Procedures—Property Management System Standards and Administrative Requirements—Management Systems and Procedures—Procurement Systems Standards and Requirements in IIA. Under the conditions specified in 45 CFR part 74.34, for-profit grantees are permitted to retain title to equipment purchased under a research grant though NIH reserves the right to order the transfer of equipment, including title, to NIH or an eligible third party named by the NIH awarding office when such third party is otherwise eligible under existing statutes. In keeping with the provisions of 45 CFR part 74.24, for-profit grantees must not use equipment acquired with NIH funds to provide services to non-Federal organizations for a fee to compete unfairly with private companies that provide equivalent services, unless the terms and conditions of the award provide otherwise, and any user charges shall be treated as program income and must be reported on the FSR. Conditions for the sale of equipment are specified at Administrative Requirements—Management Systems and Procedures—Sale of Real Property, Equipment, and Supplies in IIA.

## 18.4.2 Intellectual Property

Intellectual property requirements set forth in 37 CFR 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, but ongoing reporting remains a requirement for each invention. (See Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources in IIA.) Additional information about the requirements of 37 CFR part 401 may be obtained from the Division of Extramural Inventions and Technology Resources, OPERA, NIH (see Part III for address and telephone number).

To the extent authorized by law, the Federal government will not make public any information disclosing a Federal government-supported invention.

## 18.4.3 Program Income

Consistent with NIH Standard Terms of Award, for-profit 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 in IIA.

## 18.4.4 Operating Authorities

Awards to for-profit organizations are subject to NIH Standard Terms of Award; however, some mechanisms do not allow automatic carryover of unobligated balances of funds. Under those mechanisms, the NIH awarding IC will specify the disposition of the reported unobligated balance in the NoA. (See Administrative Requirements—Changes in Project and Budget in IIA).

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### 18.4.5 Audit

The requirements for non-Federal audits of for-profit organizations are specified in 45 CFR part 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 part 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 a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one HHS program, 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/sites/default/files/omb/assets/a133/a133_revised_2007.pdf.

The Government Auditing Standards are available electronically at http://www.gao.gov/govaud/ybk01.htm. Audits must be completed and submitted to the National External Audit Review Center within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier. The address is found in Part III.

For-profit organizations expending less than $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.

## 18.5 SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAMS

NIH is required by statute to reserve a portion of its annual extramural budget for projects under the SBIR and STTR programs. These programs primarily are intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded R&D.

Both the SBIR and STTR programs consist of the following 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.

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- ***Phase III.*** The objective of this phase, where appropriate, is for the SBC to pursue, with non-SBIR/STTR 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:

- Under SBIR Program, the Project Director/Principal Investigator (PD/PI) must have his/her primary employment with the small business concern at the time of award and for the duration of the project period, however, under the STTR Program, primary employment is not stipulated in the SBIR and STTR policy directives so NIH permits the PD/PI to have his/her primary employment with either the small business concern or the collaborating research institution. On an STTR project, the PD/PI must devote at least 10 percent of his/her time to the STTR project

- The STTR program *requires* for both phases I and II that the SBC formally partner with a single, non-profit research institution. At least 40 percent of the STTR research project is to be conducted by the SBC and at least 30 percent of the work is to be conducted by the single, "partnering" research institution through a formal, cooperative arrangement. Such organizations include universities, non-profit hospitals, and other non-profit research organizations as well as Federally Funded Research and Development Centers. STTR grants are awarded to the SBC, which will receive all of the funding for the project and disburse the appropriate funding to the research institution. The SBIR program allows subcontracting, it does not require it so the SBC may conduct the entire SBIR project without outside collaboration.

## 18.5.1 NIH Fast-Track Application Process

The NIH Fast-Track application process expedites award decisions and funding of SBIR and STTR Phase II applications for scientifically meritorious projects that have a high potential for commercialization. The Fast-Track process allows Phase I and Phase II grant applications to be submitted and reviewed together. Fast-Track applications receive a single rating. Before submitting applications for Fast-Track review, applicants are strongly encouraged to consult with cognizant NIH program staff. to assure Fast-Track is appropriate. For additional information on the submission of Fast-Track applications, see the SF424 (R&R) SBIR/STTR Application Guide available at http://grants.nih.gov/grants/funding/sbir.htm.

## 18.5.2 Eligibility

Only United States small business concerns (SBCs) are eligible to submit SBIR and STTR applications. A small business concern is one that, at the time of award for both Phase I and Phase II SBIR awards, meets *all* of the following criteria. If it appears that an applicant organization does not meet the eligibility requirements, NIH will request a size determination by the SBA. If eligibility is unclear, NIH will not make an SBIR or STTR award until the SBA provides a determination.

**a. For SBIR:**

1. Organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or
2. In the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there can be no more than 49 percent participation by business entities in the joint venture;

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3. At least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or it must be a for-profit business concern that is at least 51% owned and controlled by another for-profit business concern that is at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States -- (except in the case of a joint venture);
4. Has, including its affiliates, not more than 500 employees and meets the other regulatory requirements found in 13 CFR part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR part 121.3-2(a). The term "number of employees" is defined in 13 CFR part 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration Size District Office at http://sba.gov/size.

**b. For STTR:**

1. Organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor;
2. In the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there can be no more than 49 percent participation by business entities in the joint venture;
3. At least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States.
4. Has, including its affiliates, not more than 500 employees and meets the other regulatory requirements found in 13 CFR part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR part 121.3-2(a). The term "number of employees" is defined in 13 CFR part 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration Size District Office at http://sba.gov/size.

### 18.5.2.1 Place of Performance

For both Phase I and Phase II SBIR/STTR awards, the research or R&D project activity must be performed in its entirety in the United States. (The United States is defined as the 50 States, the territories

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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 provide compelling scientific justification in the application for the need/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. Approval will not be considered unless the application is being considered for an award. IC program officials have the authority to approve these waiver requests. Whether the request is approved or disapproved, it will be explicitly addressed in the NoA if an award is made. Whenever possible, work outside the United States, which is necessary to the completion of the project, should be supported by funding other than SBIR/STTR.

#### 18.5.2.2 Change in Organization Status & Change of Grantee Institution Actions

Applicant organization eligibility is determined at the time of the initial SBIR/STTR award. If a legal action occurs such as a merger or successor-in-interest, that changes the organization status so that they are no longer eligible for the SBIR/STTR programs, existing SBIR/STTR grants can continue. However, the organization would no longer be eligible for any new SBIR/STTR grants.

When there is a desire to transfer an SBIR/STTR grant to a different organization, the new organization must continue to meet the SBIR/STTR program eligibility requirements. Grantees should contact the NIH awarding office to discuss options when considering a move to a new organization.

#### 18.5.2.3 Minimum Level of Effort

Generally, under SBIR Phase I awards, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the SBC. Payments, in the aggregate, to consultants, consortium participants and contractors for portions of the scientific/technical effort generally may not exceed 33 percent of the total requested amount.

Generally under SBIR Phase II awards a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the SBC. In addition, payments, in the aggregate, to consultants, consortium participants, and contractors for portions of the scientific/technical effort generally may not exceed 50 percent of the total requested amount.

For STTR awards (both Phase I and Phase II), at least 40 percent of the work must be performed by the SBC and at least 30 percent of the work must be performed by the single, non-profit research institution. These percentages are Congressionally mandated and waivers are not permitted. The basis for determining the percentage of work to be performed by each of the cooperating parties is the total of direct and F&A costs attributable to each party, unless otherwise described and justified in the "Consortium/Contractual Arrangements" portion of the of the grant application.

#### 18.5.2.4 Multiple Program Director/Principal Investigator Applications and Awards

The Multiple Program Director/Principal Investigator (multiple PD/PI) option is available for NIH SBIR/STTR applicants for team science efforts. All of the policy and requirements described in Multi PD/PI apply to SBIR/STTR projects, with the exception of sections that are not relevant to the SBIR/STTR program (e.g., new investigators, multi-project applications). In addition, the following criteria apply to multiple PD/PI SBC applicants and awards:

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- The small business concern (SBC) is *always* the applicant/awardee organization. Organizations other than the SBC with PD/PIs participating in the multiple PD/PI project, including the STTR non-profit research institution partner, are subcontractors to the SBC.

- For Phase I and Phase II SBIR projects, the Contact PD/PI must meet the primary employment requirement; other PD/PIs are not required to meet the requirement. Primary employment means that more than one half of the PD/PI's time is spent in the employ of the SBC at the time of award and during the conduct of the proposed project. Deviations from this requirement are rare and must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

- For Phase I and Phase II STTR projects, the PD/PI is not required to be employed by the SBC. However, the Contact PD/PI, the first PD/PI listed, must have a formal appointment with, or commitment to, the SBC, which must be in the form of an official relationship between the parties, but need not include a salary or other form of remuneration. Each PD/PI on a multiple PD/PI award must commit a minimum of 1.2 calendar months (10% effort) to the project.

- An STTR applicant organization must officially affiliate a PD/PI with the SBC in the eRA Commons if the PD/PI is not an employee of the SBC.

- A Phase II Competing Renewal submitted as a multiple PD/PI application requesting support for a project previously supported through a single PD/PI award should state the changes in the Project's direct and management that led to the proposed multiple PD/PI model.

## 18.5.3 Public Policy Requirements and Objectives

For-profit organizations receiving SBIR/STTR awards generally are subject to the same public policy requirements as non-profit organizations. However, the requirements concerning disclosure of financial conflicts of interest (see Public Policy Requirements, Objectives, and Other Appropriation Mandates—Financial Conflict of Interest in IIA) do not apply to applications or awards under Phase I of the SBIR/STTR programs. The requirements do, however, apply to Phase II applications and awards.

## 18.5.4 Allowable Costs and Fee

### 18.5.4.1 Program Levels (Total Costs)

SBA SBIR and STTR Policy Directives provide program levels for SBIR and STTR programs based on statutory guidelines. However, these directives also give agencies discretion to exceed these levels when the proposed budget and requested period of support are fully justified and scientifically appropriate in relation to the proposed research. In general the levels are:

- SBIR Phase I: $150,000 Total Costs; 6 months

- SBIR Phase II: $1,000,000 Total Costs; 2 years

- STTR Phase I: $100,000 Total Costs; 1 year

- STTR Phase II: $750,000 Total Costs; 2 years

Some ICs offer Phase II SBIR/STTR awardees the opportunity to apply for Phase II Competing Renewal awards. These are available for those projects that require extraordinary time and effort in the R&D phase

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and may or may not require FDA approval for the development of such projects, including drugs, devices, vaccines, therapeutics, and medical implants related to the mission of the IC. Only those small business concerns who have been awarded a Phase II are eligible to apply for the Phase II Competing Renewal award. Program levels are:

- SBIR Phase II Competing Renewals (Phase II "B"): $3,000,000; 3 years
- STTR Phase II Competing Renewals (Phase II "B"): $3,000,000; 3 years

Applicants must request an appropriate level in the competing application; applications will not be adjusted after submission.

### 18.5.4.2 Profit or Fee

A reasonable profit or fee may be paid to a SBC receiving an award under Phase I or Phase II of the SBIR and STTR programs. The profit or fee is not considered a "cost" for purposes of determining allowable use, program income accountability, or audit thresholds. The profit or fee may be used by the SBC for any purpose, including additional effort under the SBIR/STTR award. It is intended to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work; however, the amount of the profit or fee normally will not exceed seven (7) percent of total costs (direct and F&A) for each phase of the project. The profit or fee should be drawn from PMS in increments proportional to the drawdown of funds for direct and F&A costs. The profit or fee applies solely to the SBC receiving the SBIR/STTR award and not to any other participant; however, in accordance with normal commercial practice, the SBC may pay a profit or fee to a contractor providing routine goods or services to the SBC under the grant.

### 18.5.4.3 Facilities and Administrative Costs (Indirect Costs)

#### 18.5.4.3.1 Phase I

If the applicant SBC has a currently effective F&A cost rate(s) with a Federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. NIH ICs use the term F&A costs for all types of applicants and recipients; however, for-profit organizations will find that DFAS and organizations external to NIH refer to these costs as indirect costs. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose estimated F&A costs at a rate not to exceed 40 percent of the total direct costs. However, SBCs are reminded that only actual F&A costs are to be charged to projects. (If awarded at a rate of 40 percent or less, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with a Federal agency.) NIH will not negotiate indirect cost rates for Phase I awards.

#### 18.5.4.3.2 Phase II

If the applicant SBC has a currently effective negotiated indirect cost rate(s) with a Federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose an estimated F&A rate in the application. If the requested F&A cost rate is 40 percent of total direct costs or less, no further justification is required at the time of award, and F&A costs will be awarded at the requested rate. However, SBCs are reminded that only actual F&A costs may be charged to projects. If awarded at a rate of 40 percent or less of total direct costs, the rate used to charge

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actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with DFAS. DFAS—the office authorized to negotiate indirect cost rates with SBC's receiving NIH SBIR/STTR awards—will negotiate indirect cost rates for SBCs receiving Phase II awards that requested a rate greater than 40 percent of total direct costs.

Upon request, the applicant SBC should provide DFAS with an indirect cost proposal and supporting financial data for its most recently completed fiscal year. If financial data is not available for the most recently completed fiscal year, the applicant should submit a proposal showing estimated rates with supporting documentation. Further information about DFAS is available at its Web site or by telephone (see Part III).

## 18.5.5 Administrative Requirements

For-profit organizations that receive SBIR/STTR awards generally are subject to the same administrative requirements as non-profit organizations.

### 18.5.5.1 Market Research

NIH will not support market research, including studies of the literature that lead to a new or expanded statement of work, under the grant. For purposes of the SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the proposed research. It includes various types of research, such as the size of potential markets and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that include a survey of the public as part of the objectives of the project to determine the impact of the subject of the research on the behavior of individuals.

### 18.5.5.2 Intellectual Property

Rights to data, including software developed under the terms of any funding agreement resulting from an NIH award, shall remain with the 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.

***Rights in Data Developed Under SBIR Funding Agreement.*** The Small Business Innovation Research Program Reauthorization Act of 2000, Public Law 106-554, amended section 9 of the Act (15 U.S.C. 638), referred to as the "Act" provides for "retention by an SBC of the rights to data generated by the concern in the performance of an SBIR award."

1. Each agency must refrain from disclosing SBIR technical data to outside the Government (except reviewers) and especially to competitors of the SBC, or from using the information to produce future technical procurement specifications that could harm the SBC that discovered and developed the innovation.
2. SBIR agencies must protect from disclosure and non-governmental use all SBIR technical data developed from work performed under an SBIR funding agreement for a period of not less than four years from delivery of the last deliverable under that agreement (either Phase I, Phase II, or Federally-funded SBIR Phase III) unless, subject to (b)(3) of this section, the agency obtains

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permission to disclose such SBIR technical data from the awardee or SBIR applicant. Agencies are released from obligation to protect SBIR data upon expiration of the protection period except that any such data that is also protected and referenced under a subsequent SBIR award must remain protected through the protection period of that subsequent SBIR award. For example, if a Phase III award is issued within or after the Phase II data rights protection period and the Phase III award refers to and protects data developed and protected under the Phase II award, then that data must continue to be protected through the Phase III protection period. Agencies have discretion to adopt a protection period longer than four years. The Government retains a royalty-free license for Government use of any technical data delivered under an SBIR award, whether patented or not. This section does not apply to program evaluation.

3. SBIR technical data rights apply to all SBIR awards, including subcontracts to such awards, that fall within the statutory definition of Phase I, II, or III of the SBIR Program, as described in Section 4 of this Policy Directive. The scope and extent of the SBIR technical data rights applicable to Federally-funded Phase III awards is identical to the SBIR data rights applicable to Phases I and II SBIR awards. The data rights protection period lapses only: (i) Upon expiration of the protection period applicable to the SBIR award, or (ii) by agreement between the awardee and the agency.

4. Agencies must insert the provisions of (b)(1), (2), and (3) immediately above as SBIR data rights clauses into all SBIR Phase I, Phase II, and Phase III awards. These data rights clauses are non- negotiable and must not be the subject of negotiations pertaining to an SBIR Phase III award, or diminished or removed during award administration. An agency must not, in any way, make issuance of an SBIR Phase III award conditional on data rights. If the SBIR awardee wishes to transfer its SBIR data rights to the awarding agency or to a third party, it must do so in writing under a separate agreement. A decision by the awardee to relinquish, transfer, or modify in any way its SBIR data rights must be made without pressure or coercion by the agency or any other party. Following issuance of an SBIR Phase III award, the awardee may enter into an agreement with the awarding agency to transfer or modify the data rights contained in that SBIR Phase III award. Such a bilateral data rights agreement must be entered into only after the SBIR Phase III award, which includes the appropriate SBIR data rights clause, has been signed. SBA must immediately report to the Congress any attempt or action by an agency to condition an SBIR award on data rights, to exclude the appropriate data rights clause from the award, or to diminish such rights.

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 Web site at http://grants.nih.gov/grants/funding/sbir.htm.) By signing the face page of the grant application, the SBC's AOR 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 IC.

SBIR/STTR grantees are covered by 35 U.S.C. 200-212 and 37 CFR part 401 with respect to inventions and patents (see Grants to For-Profit Organizations—Administrative Requirements—Intellectual Property in this chapter).

### 18.5.5.3 Data Sharing

Applicants for SBIR Phase II funding of $500,000 or more of direct costs in any single year must comply with 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

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indicated under Intellectual Property in this chapter, whether or not the award meets the threshold for data sharing, NIH will not release data outside the Federal government without the grantee's permission for a period of 4 years from completion of the project. The entire policy may be found at http://grants.nih.gov/grants/policy/data_sharing.

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# 19 RESEARCH PATIENT CARE COSTS

## 19.1 GENERAL

This chapter provides NIH policy on the determination and reimbursement of research patient care costs under grants. This general policy is intended to be applied in conjunction with the requirements of 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.

## 19.2 DEFINITIONS

***Research Patient Care Costs.*** The costs of routine and ancillary services provided by hospitals to individuals participating in research programs. The costs of these services normally are assigned to specific research projects through the development and application of research patient care rates or amounts (hereafter "rates"). Research patient care costs do not include: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors, (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service , (3) recruitment or retention fees or (4) the data management or statistical analysis of clinical research results.

***Hospital.*** Includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria.

***Research Patients.*** Inpatient and outpatient subjects, volunteers, or donors participating in a research protocol.

***Routine Services.*** Regular room services, minor medical and surgical supplies, and the use of equipment and facilities, for which a separate charge is not customarily made.

***Ancillary Services.*** Those special services for which charges are customarily made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology.

***Outpatient Services.*** Services rendered to subjects/volunteers/donors who are not hospitalized.

***Usual Patient Care.*** Items and services (routine and ancillary) ordinarily furnished in the treatment of patients by providers of patient care under the supervision of the physician or other responsible health professional. Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional health services. These expenses are for care that would have been incurred even if the research study did not exist. The patient and/or third-party insurance generally will provide for reimbursement of charges for "usual patient care" as opposed to not reimbursing those charges generated solely because of participation in a research protocol.

***Discrete Centers.*** Groups of beds that have been set aside for occupancy by research patients and are physically separated from other hospital beds in an environment that normally permits an ascertainable allocation of costs associated with the space they occupy and the service needs they generate.

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***Scatter Beds.*** Beds assigned to research patients based on availability. These beds are not physically separate from nonresearch beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital and are not usually distinguishable in terms of services or costs from other general service beds within the hospital.

***Cost-Finding Process.*** The technique of apportioning or allocating the costs of the non-revenue-producing cost centers to each other and to the revenue-producing centers on the basis of the statistical data that measure the amount of service rendered by each center to other centers.

## 19.3 POLICY

NIH provides funds for research patient care costs under grants and cooperative agreements. Research patients may receive routine services as inpatients or ancillary services as either inpatient or outpatient subjects/volunteers/donors. In order to receive reimbursement for research patient care costs, any hospital that, as a direct recipient of NIH funds, expects to incur more than $100,000 in patient care costs in any single budget period on a single NIH grant must either have in place or take steps to negotiate a research patient care rate agreement with the cognizant 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 patient care for all consortium participants/contractors under grants no matter the dollar figure are subject to the requirements specified in the subsection on Special Procedures for Certain Hospitals below. Failure to negotiate a research patient care rate with DCA when required may result in the disallowance of all research patient care costs charged to a grant.

## 19.4 ALLOWABLE COSTS

The type of patient and services received are the determining factors for allowing research patient care costs as charges to NIH grants. If the patient is receiving service or care that neither differs from usual patient care nor results in expenses greater than those that would have been incurred if the study had not existed, then the patient is considered to be hospitalized for usual care purposes and the grant will generally not support the costs. When the research extends the period of hospitalization beyond that ordinarily required for usual care, or imposes procedures, tests or services beyond usual care, whether in an inpatient or outpatient setting, the grant may pay the additional costs. The 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. Acceptable exceptions are listed below.

NIH funds may be used to pay all costs (whether usual care costs or research care costs) for the entire period of hospitalization or research tests or services for individuals who would not have been hospitalized or received such tests or services except for their participation in the research study. Any such exceptions should be documented in the grantee's records. These individuals may include the following:

- Volunteers to whom no health advantages may be expected to accrue as a result of the hospitalization. Examples would be normal controls for metabolic or other studies; people with genetic or certain abnormalities of interest to the investigator; healthy individuals participating in a

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clinical trial, for example a vaccine trial; and sick people brought to the hospital solely for studies when they otherwise would not require hospitalization.

- Volunteers who are sick and of research importance to the protocol but economically unable or without funds available to them through a responsible third party to pay hospitalization expenses. This includes patients for whom some third-party payer, such as a city, county, or State government, might pay hospitalization expenses in some other hospital but has no responsibility to pay in the hospital in which the approved clinical research is being conducted.

- Volunteers of research importance who are unwilling to spend their own money or use their hospital plan coverage at that particular time. (Fear of more urgent need in the future for both personal funds and health insurance might be one reason for the patient's reluctance to participate in the study.) The investigator has a special responsibility in making the decision to include patients in this group with full charges to the grant, since NIH expects the patient and/or third party to pay the total costs of usual care. However, in exceptional circumstances, the investigator may decide to pay the total expenses for hospitalization, research services, or tests from the grant if this is required to secure timely cooperation of a valuable study patient not otherwise available.

### 19.4.1 Computing Research Patient Care Costs

Research patient care costs, whether expressed as a rate or an amount, shall be computed in an amount consistent with the principles and procedures used by the Medicare program for determining the portion of Medicare reimbursement based on reasonable costs. Separate cost centers must be established for each discrete bed unit for purposes of allocating or distributing allowable routine costs to the discrete unit.

When provisional rates are used as the basis for award of research patient care costs, the amount awarded shall constitute the maximum amount that the NIH awarding IC is obligated to reimburse the grantee for such costs. Provisional rates must be adjusted if a lower final rate is negotiated.

### 19.4.2 Facilities and Administrative Costs

F&A costs should not be paid on any cost component representing the cost of research patient care activities. Research patient care rates (routine and ancillary) include F&A costs related to "hospital-type" employees (nurses, medical technicians, and similar personnel) supported as a direct cost under a grant. Therefore, to preclude over-recoveries of costs similar to these F&A costs, salaries and wages of all "hospital-type" employees working on the grant must be excluded from the salary and wage (S&W) base used to claim F&A costs. Related fringe benefits also should be excluded if such costs are part of the S&W base. If a "total-direct-costs" base is used to compute and claim F&A costs, the above-mentioned "hospital-type" salaries also must be excluded from the base as well as any other base costs chargeable to the grant through the application of a research patient care rate.

If the grant or a consortium agreement/contract under a grant provides funding exclusively for research patient care activities, no F&A costs normally will be allowed as a separate cost element since all allocable F&A costs will be accounted for in the routine or ancillary activity costs contained in research patient care rates.

Although foreign organizations are not prohibited from requesting research patient care costs, all F&A expenses must be excluded from the charges to the grant.

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## 19.4.3 Special Procedures for Certain Hospitals

### 19.4.3.1 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 chapter, but has a currently negotiated research patient care rate, that rate will be used in awarding and reimbursing research patient care costs, regardless of the amount that the 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.

### 19.4.3.2 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 chapter, 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 chapter), 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.

## 19.4.4 Financial Responsibilities

If the costs of patient care are funded by the grant, and whether those costs are classified as usual patient care or research patient care, the amount recovered from third parties must be credited to the grant. However, patient charges must be adjusted for both routine services and ancillaries prior to applying the third-party recoveries. The 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 chapter), the total bill must be adjusted to cost before applying any third-party recoveries. The remaining balance of allowable costs may then be charged to the grant.

In certain circumstances, funds may be awarded that support tests specifically developed for research purposes that are subsequently billed to third parties. In such cases, funds recovered from third parties must be credited to the grant account.

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## 19.5 PROGRAM REQUIREMENTS

An individual NIH IC/program may adopt special implementing procedures consistent with this section to meet its own specific needs.

## 19.6 POST-AWARD REQUIREMENTS

Post-award rebudgeting into or out of the patient care costs category is likely to be considered a change in scope and require prior approval of the NIH awarding IC (see Administrative Requirements - Prior Approval Requirements - Change in Scope in IIA).

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# Part III: Points of Contact

Various offices and officials are mentioned throughout the preceding parts of the NIHGPS as sources of information or as responsible for certain activities in the NIH grants process. Contact information for these and other offices and officials is provided in this part. These addresses should not be used for express mail or other types of hand-deliveries. The IC should be contacted to obtain the address to use for express mail.

For each IC that awards grants, a listing is provided for the CGMO as well as an extramural program official that may be contacted for general information. The web address for the IC's home page also is included. Requests related to particular applications submitted or grants awarded should be directed to the individual(s) specified in formal communications from NIH, e.g., in the NoA.

## 20 INSTITUTES AND CENTERS

| Institute/Center | Chief Grants Management Officer | Extramural Program Official |
|---|---|---|
| John E. Fogarty International Center (FIC)<br>http://www.fic.nih.gov/ | Building 31C, Room B2C29, MSC-2220<br>Bethesda, MD 20892-2220<br>301/451-1670<br>301/594-1211 (fax) | Building 31C, Room B2C29, MSC-2220<br>Bethesda, MD 20892-2220<br>301/496-1653<br>301/402-0779 (fax) |
| National Cancer Institute (NCI)<br>http://www.nci.nih.gov | 6120 Executive Boulevard Executive Plaza South, Room 234, MSC-7148<br>Bethesda, MD 20892-7150<br>301/496-7753<br>301/402-3409 (fax) | 6116 Executive Boulevard Executive Plaza North, Suite 8001, MSC-8327<br>Bethesda, MD 20892-7405<br>301/496-5147<br>301/402-0956 (fax) |
| National Center for Complementary and Alternative Medicine (NCCAM)<br>http://nccam.nih.gov | 6707 Democracy Boulevard, II Suite 401, MSC-5475<br>Bethesda, MD 20892-5475<br>301/451-6330<br>301/480-1552 (fax) | 6707 Democracy Boulevard, II Suite 401, MSC-5475<br>Bethesda, MD 20892-5475<br>301/594-2014<br>301/480-2419 (fax) |
| National Center for Research Resources (NCRR)<br>http://www.ncrr.nih.gov | 6701 Democracy Boulevard One Democracy Plaza, Suite 1036, MSC-4874<br>Bethesda, MD 20892-4874<br>301/435-0844<br>301/480-3777 (fax) | 6701 Democracy Boulevard One Democracy Plaza, Room 902, MSC-4874<br>Bethesda, MD 20892-4874<br>301/435-0879<br>301/480-3658 (fax) |
| National Eye Institute (NEI)<br>http://www.nei.nih.gov | 5635 Fishers Lane, Suite 1300, MSC-9300<br>Bethesda, MD 20892-9300<br>301/451-2020<br>301/496-9997 (fax) | 5635 Fishers Lane, Suite 1300, MSC-9300<br>Bethesda, MD 20892-9300<br>301/451-2020<br>301/402-0528 (fax) |

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| Institute/Center | Chief Grants Management Officer | Extramural Program Official |
|---|---|---|
| National Heart, Lung and Blood Institute (NHLBI)<br>http://www.nhlbi.nih.gov | 6701 Rockledge Drive<br>Rockledge II, Room 7160,<br>MSC-7926<br>Bethesda, MD 20892-7926<br>301/435-0166<br>301/480-3310 (fax) | 6701 Rockledge Drive<br>Rockledge II, Room 7100,<br>MSC-7922<br>Bethesda, MD 20892-7922<br>301/435-0260<br>301/480-1124 (fax) |
| National Human Genome Research Institute (NHGRI)<br>http://www.nhgri.nih.gov or<br>http://www.genome.gov | 5635 Fishers Lane, Suite 4076,<br>MSC-9306<br>Bethesda, MD 20892-9306<br>301/435-7858<br>301/451-5434 (fax) | 5635 Fishers Lane, Suite 4080,<br>MSC-9305<br>Bethesda, MD 20892-2033<br>301/496-7531<br>301/480-2770 (fax) |
| National Institute on Aging (NIA)<br>http://www.nia.nih.gov | 7201 Wisconsin Avenue<br>Gateway Bldg., Room 2N212,<br>MSC-9205<br>Bethesda, MD 20892-9205<br>301/496-1472<br>302/402-3672 (fax) | 7201 Wisconsin Avenue<br>Gateway Bldg., Room 2C218F,<br>MSC-9205<br>Bethesda, MD 20892-9205<br>301/402-7715<br>301/402-2945 (fax) |
| National Institute on Alcohol Abuse and Alcoholism (NIAAA)<br>http://www.niaaa.nih.gov | 5635 Fishers Lane, Room 3023,<br>MSC-9304<br>Bethesda, MD 20892-9304<br>301/443-4704<br>301/443-3891 (fax) | 5635 Fishers Lane, Room 2085,<br>MSC-9304<br>Bethesda, MD 20892-9304<br>301/443-9737<br>301/443-6077 (fax) |
| National Institute of Allergy and Infectious Diseases (NIAID)<br>http://www.niaid.nih.gov | 6700-B Rockledge Drive, Room 2116, MSC-7614<br>Bethesda, MD 20892-7614<br>301/496-7075<br>301/480-2599 (fax) | 6700-B Rockledge Drive, Room 2141, MSC-7610<br>Bethesda, MD 20892-7610<br>301/496-7291<br>301/402-0369 (fax) |
| National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)<br>http://www.niams.nih.gov | 6701 Democracy Boulevard<br>One Democracy Plaza, Suite 800, MSC-4872<br>Bethesda, MD 20892-4872<br>301/594-3535<br>310/480-5450 (fax) | 6701 Democracy Boulevard<br>One Democracy Plaza, Suite 800, MSC-4872<br>Bethesda, MD 20892-4872<br>301/594-2463<br>301/480-4543 (fax) |
| National Institute of Biomedical Imaging and Bioengineering (NIBIB)<br>http://www.nibib.nih.gov | 6707 Democracy Boulevard,<br>Suite 900, MSC-5469<br>Bethesda, MD 20892-5469<br>301/451-4782<br>301/480-4974 (fax) | 6707 Democracy Boulevard,<br>Suite 200, MSC-5477<br>Bethesda, MD 20892-5477<br>301/402-7039<br>301/480-4973 (fax) |
| *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)<br>http://www.nichd.nih.gov | 6100 Executive Boulevard,<br>Room 8A01A<br>MSC-7510<br>Bethesda, MD 20892-7510<br>301/496-5001<br>301/480-4782 (fax) | 6100 Executive Boulevard,<br>Room 6154,<br>MSC-7510<br>Bethesda, MD 20892-7510<br>301/435-6856<br>301/402-2083 (fax) |

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| Institute/Center | Chief Grants Management Officer | Extramural Program Official |
|---|---|---|
| National Institute on Deafness and Other Communication Disorders (NIDCD)<br>http://www.nidcd.nih.gov | 6120 Executive Boulevard<br>Executive Plaza South, Suite 400B, MSC-7180<br>Bethesda, MD 20892-7180<br>301/402-0909<br>301/402-1758 (fax) | 6120 Executive Boulevard<br>Executive Plaza South, Suite 400C, MSC-7180<br>Bethesda, MD 20892-7180<br>301/496-8693<br>301/402-6250 (fax) |
| National Institute of Dental and Craniofacial Research (NIDCR)<br>http://www.nidcr.nih.gov | 6701 Democracy Boulevard,<br>Room 658, MSC-4878<br>Bethesda, MD 20892-4878<br>301/594-4808<br>301/480-3562 (fax) | 6701 Democracy Boulevard,<br>Room 660, MSC-4878<br>Bethesda, MD 20892-4878<br>301/594-4805<br>301/480-8303 (fax) |
| National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)<br>http://www.niddk.nih.gov | 6707 Democracy Boulevard<br>2 Democracy Plaza, Room 731, MSC-5450<br>Bethesda, MD 20892-5450<br>301/594-8854<br>301/480-3504 (fax) | 6707 Democracy Boulevard<br>2 Democracy Plaza, Room 715, MSC-5453<br>Bethesda, MD 20892-5453<br>301/594-8834<br>301/480-3504 (fax) |
| National Institute on Drug Abuse (NIDA)<br>http://www.nida.nih.gov | 6001 Executive Boulevard<br>Neuroscience Center,<br>Suite 4128, MSC-9560<br>Bethesda, MD 20892-9560<br>301/443-6710<br>301/594-6849 (fax) | 6101 Executive Boulevard<br>Neuroscience Center, Suite 200, MSC-8401<br>Bethesda, MD 20892-8401<br>301/443-2755<br>301/443-0538 (fax) |
| National Institute of Environmental Health Sciences (NIEHS)<br>http://www.niehs.nih.gov | 79 T.W. Alexander Drive, MSC EC-22<br>Research Triangle Park, NC 27709<br>919/541-2749<br>919/541-2860 (fax) | 615 Davis Drive,<br>Durham, NC 27713<br>919/541-7723<br>919/541-2843 (fax) |
| National Institute of General Medical Sciences (NIGMS)<br>http://www.nigms.nih.gov | 45 Center Drive<br>Natcher Bldg., Room 2AN32C., MSC-6200<br>Bethesda, MD 20892-6200<br>301/594-5520<br>301/480-1969 (fax) | 45 Center Drive<br>Natcher Bldg., Room 2AN.24H, MSC-6200<br>Bethesda, MD 20892-6200<br>301/594-4499<br>301/480-1852 (fax) |
| National Institute of Mental Health (NIMH)<br>http://www.nimh.nih.gov | 6001 Executive Boulevard<br>Neuroscience Center, Room 6122, MSC 9605<br>Bethesda, MD 20892-9605<br>301/443-2811<br>301/480-1965 (fax) | 6001 Executive Boulevard<br>Neuroscience Center, Room 6154, MSC-9609<br>Bethesda, MD 20892-9609<br>301/443-3367<br>301/443-4720 (fax) |
| National Institute on Minority Health and Health Disparities (NIMHD)<br>http://www.ncmhd.nih.gov | 6707 Democracy Boulevard,<br>Suite 800, MSC 5464<br>Bethesda, MD<br>301/594-8412<br>301/480-4049 (fax) | 6707 Democracy Boulevard,<br>Suite 800, MSC 5465<br>Bethesda, MD<br>301/402-1366<br>301/402-4049 (fax) |

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| Institute/Center | Chief Grants Management Officer | Extramural Program Official |
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| National Institute of Neurological Disorders and Stroke (NINDS)<br>http://www.ninds.nih.gov | 6001 Executive Boulevard<br>Neuroscience Center, Room 3254, MSC-9537<br>Bethesda, MD 20892-9537<br>301/496-9231<br>301/402-0219 (fax) | 6001 Executive Boulevard<br>Neuroscience Center, Room 3307, MSC-9531<br>Bethesda, MD 20892-9531<br>301/496-9248<br>301/402-4370 (fax) |
| National Institute of Nursing Research (NINR)<br>http://www.nih.gov/ninr | 6701 Democracy Boulevard<br>One Democracy Plaza, Suite 710, MSC-4870<br>Bethesda, MD 20892-4870<br>301/594-6869<br>301/402-4502 (fax) | 6701 Democracy Boulevard<br>One Democracy Plaza, Suite 710, MSC-4870<br>Bethesda, MD 20892-4870<br>301/402-7889<br>301/480-4969 (fax) |
| National Library of Medicine (NLM)<br>http://www.nlm.nih.gov | 6705 Rockledge Drive<br>Rockledge I, Suite 301, MSC-7968<br>Bethesda, MD 20892-7968<br>301/496-4222<br>301/402-0421 (fax) | 6705 Rockledge Drive<br>Rockledge I, Suite 301, MSC-7968<br>Bethesda, MD 20892-7968<br>301/496-4621<br>301/402-0421 (fax) |

## 20.1 OTHER NIH OFFICES

| NIH Office | Address |
|---|---|
| Division of Grants Policy<br>Office of Policy for Extramural Research Administration (OPERA)<br>Office of Extramural Research | 6705 Rockledge Drive, Suite 350<br>Rockledge I, MSC-7974<br>Bethesda, MD 20892-7974<br>301/435-0949<br>301/435-3059 (fax)<br>E-mail: GrantsPolicy@mail.nih.gov |
| Division of Grants Compliance and Oversight<br>Office of Policy for Extramural Research Administration (OPERA)<br>Office of Extramural Research | 6705 Rockledge Drive, Suite 350<br>Rockledge I, MSC-7974<br>Bethesda, MD 20892-7974<br>301/435-0938<br>301/435-3059 (fax)<br>E-mail: GrantsCompliance@mail.nih.gov<br>Financial Conflicts of Interest<br>E-mail: FCOICompliance@mail.nih.gov |
| Division of Extramural Inventions and Technology Resources Branch<br>Office of Policy for Extramural Research Administration (OPERA)<br>Office of Extramural Research | 6705 Rockledge Drive, Suite 310<br>Rockledge I, MSC-7980<br>Bethesda, MD 20892-7980<br>301/435-1986<br>301/480-0272 (fax)<br>E-mail: Edison@nih.gov<br>Inventions@nih.gov |

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| NIH Office | Address |
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| Division of Communications and Outreach<br>Office of Planning and Communication<br>Office of Extramural Research<br><br>Grants Information (general grants information) | 6705 Rockledge Drive, Suite 5040<br>301/435-0714<br>E-mail: GrantsInfo@nih.gov<br>http://www.nih.gov/grants/oer.htm |
| Division of Extramural Activities Support<br>Office of Extramural Research | Centralized Mailing Address for Annual Progress Reports (T-5s):<br><br>Division of Extramural Activities Support, OER<br>National Institutes of Health<br>6705 Rockledge Drive, Room 2207, MSC 7987<br>Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)<br>Bethesda, MD 20817 (for other courier/express mail delivery only)<br>Phone Number: 301/594-6584<br>E-mail: DeasCentralized@od.nih.gov |
| Division of Extramural Activities Support<br>Office of Extramural Research | Centralized Mailing Address for hard copy submission of Closeout Documents:<br><br>NIH Central Closeout Center<br>6705 Rockledge Drive, RM 2207, MSC 7987<br>Bethesda, MD 20892 (for regular or U.S. Postal Service Express mail)<br>Bethesda, MD 20817 (for other courier/express deliveries only)<br><br>Phone Number: 301/594-6584<br>Fax: 301/480-2304<br>E-mail: DeasCentralized@od.nih.gov |
| Office of Extramural Programs<br>Office of Extramural Research<br><br>E-mail: OEPMailbox@mail.nih.gov<br><br>http://grants.nih.gov/grants/oer_offices/oep.htm | 1. For issues regarding NRSA Payback contact:<br><br>Division of Loan Repayment<br>NRSA Payback Service Center<br>6011 Executive Blvd., Room 206<br>Bethesda, MD 20892-7650<br>Phone Number: 1-866-298-9371<br>E-mail: nrsapaybackcenter@mail.nih.gov<br><br>2. For issues regarding Peer Review, Human Research Protections and Research Training contact:<br><br>Division of Scientific Programs<br>6705 Rockledge 1, Room 3520<br>Bethesda, MD 20892-7982<br>301/435-1418<br>301/480-0146 (fax) |

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| NIH Office | Address |
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| | 3. For issues regarding SBIR/STTR Programs, AREA grants and conference grants contact:<br><br>Division of Special Programs<br>6705 Rockledge 1, Room 3522<br>Bethesda, MD 20892-7982<br>301/435-2688<br>301/480-0146 (fax)<br><br>Web sites for these topic areas can be found from the main OER Grants site:<br>http://grants.nih.gov/grants/oer.htm |
| Office of Laboratory Animal Welfare (OLAW)<br>Office of Extramural Research<br><br>http://grants.nih.gov/grants/olaw/olaw.htm | 6705 Rockledge Drive, Suite 360<br>Rockledge I, MSC-7982<br>Bethesda, MD 20892-7982<br>301/496-7163<br>301/915-9481 (fax)<br>E-mail: OLAW@mail.nih.gov |
| Center for Scientific Review (CSR)<br>http://www.csr.nih.gov | Division of Receipt and Referral<br>6701 Rockledge Drive<br>Rockledge II, MSC-7768<br>Bethesda, MD 20892-7768<br>301/435-1115 |
| Center for Scientific Review (CSR)<br>http://www.csr.nih.gov | For submission of paper competing applications;<br><br>Center for Scientific Review<br>National Institutes of Health<br>Suite 1040<br>6701 Rockledge Drive, MSC-7710<br>Bethesda, MD 20892-7710 (zip code for applications sent by USPS regular or Express mail)<br>Bethesda, MD 20817 (zip code for applications sent using a courier service) |
| Office of Biotechnology Activities (OBA)<br>http://oba.od.nih.gov/oba | 6705 Rockledge Drive<br>Suite 750, MSC-7985<br>Bethesda, MD 20892-7985<br>301/496-9838<br>301/496-9839 (fax)<br>E-mail: oba@mail.nih.gov |
| Office of Intramural Research (OIR)<br>http://www1.od.nih.gov/oir/sourcebook/oir/oir-staff.htm#OIR | 1 Center Drive<br>Building 1, Room 160<br>Bethesda, MD 20892-0151<br>301/496-1921<br>301/402-4273 (fax) |

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| NIH Office | Address |
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| Office of Financial Management (OFM)<br>http://ofm.od.nih.gov | Office of Financial Management<br>2115 East Jefferson Street<br>Bethesda, MD 20892-8500<br>301/402-9123<br>301/402-4934 (fax)<br><br>Electronic submission of Financial Status Reports:<br>https://commons.era.nih.gov/commons |
| Division of Financial Advisory Services (DFAS)<br>Office of Acquisition Management and Policy (OAMP)<br>http://oamp.od.nih.gov/dfas/dfas.asp | 6011 Executive Boulevard, Room 549C<br>MSC-7663<br>Bethesda, MD 20892-7663<br>301/496-4401<br>301/402-0177 (fax) |
| Office of Management Assessment (OMA)<br>http://oma.od.nih.gov/pi/ | Report allegations of non-criminal use of grant funds to:<br><br>Division of Program Integrity<br>6011 Executive Boulevard, Suite 601, MSC-7669<br>Bethesda, MD 20892-7669<br>301/496-5586<br>301/480-1204 (fax) |

## 20.2 OTHER HHS AND GOVERNMENT OFFICES

| Office | Address |
|---|---|
| Advisory Council on Historic Preservation<br>http://www.achp.gov | 1100 Pennsylvania Avenue NW<br>Washington, DC 20004<br>202-606-8503 |
| Office of the Inspector General (OIG)<br>http://www.oig.hhs.gov | Report allegations of criminal offenses to:<br><br>Office of Inspector General<br>Department of Health and Human Services<br>Attn: HOTLINE<br>PO Box 23489<br>Washington, DC 20026<br>1-800/HHS-TIPS (1-800-447-8477)<br>E-mail: HHSTips@oig.hhs.gov<br>http://oig.hhs.gov/fraud/hotline<br>TTY: 1-800-377-4950<br>Fax: 1-800-223-8164 |

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| Office | Address |
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| Office of the Inspector General (OIG)<br>http://www.oig.hhs.gov | Questions concerning A-133 audit requirements:<br>HHS National External Audit Review Center<br>Office of Audit Services<br>1100 Walnut St, Suite 850<br>Kansas City, Missouri 64106<br>1-800/732-0679 (voice)<br>816/426-7720 (voice)<br>816/426-7745 (fax)<br>http://harvester.census.gov/sac |
| Office for Human Research Protections (OHRP)<br>http://www.hhs.gov/ohrp/ | The Tower Building<br>1101 Wootton Parkway, Suite 200<br>Rockville, MD 20852<br>240/453-6900<br>Toll Free within the U.S. 1-866/447-4777<br>E-mail: OHRP@hhs.gov |
| Office of Research Integrity (ORI)<br>http://ori.dhhs.gov | The Tower Building<br>1101 Wootton Parkway, Suite 750<br>Rockville, MD 20852<br>240/453-8400<br>E-mail: askori@hhs.gov |
| Departmental Appeals Board (DAB)<br>http://www.hhs.gov/dab/ | 330 Independence Avenue, SW<br>Cohen Building, Room G-644, MS 6127<br>Washington, DC 20201<br>202/565-0200 |
| Office for Civil Rights (OCR)<br>http://www.hhs.gov/ocr | Headquarters<br>200 Independence Avenue, SW<br>Hubert H. Humphrey Building Bldg., Room 509 F<br>Washington, DC 20201<br>1-800/368-1019 |
| Program Support Center (PSC)<br>Financial Management Service<br>Division of Payment Management (DPM)<br>http://www.dpm.psc.gov | P.O. Box 6021<br>Rockville, MD 20852<br>1-877/614-5533 (PMS Help Desk)<br>301/443-8362 (fax)<br>E-mail: PMSSupport@psc.gov<br><br>Payment Management System:<br>http://www.dpm.psc.gov/Contact.aspx |

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| Office | Address |
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| Division of Cost Allocation (DCA)<br>http://rates.psc.gov/ | Mid-Atlantic Field Office<br><br>(Services Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia and West Virginia)<br><br>330 Independence Avenue, S.W.<br>Cohen Building, Room 10-67<br>Washington, DC 20201<br>202/401-2808<br>http://rates.psc.gov/fms/dca/midatlantic.html |
| Division of Cost Allocation (DCA)<br>http://rates.psc.gov/ | Northeastern Field Office<br><br>(Services Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Puerto Rico, the Virgin Islands, Canada and Europe)<br><br>26 Federal Plaza<br>Room 41-122<br>New York, NY 10278<br>212/264-2069<br>http://rates.psc.gov/fms/dca/northeastern.html |
| Division of Cost Allocation (DCA)<br>http://rates.psc.gov/ | Central States Field Office<br><br>(Services Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, New Mexico, Ohio, Oklahoma, Texas and Wisconsin)<br><br>1301 Young Street<br>Room 732<br>Dallas, TX 75202<br>214/767-3261<br>http://rates.psc.gov/fms/dca/central.html |
| Division of Cost Allocation (DCA)<br>http://rates.psc.gov/ | Western Field Office<br><br>(Services Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, Australia, and Asia)<br><br>90 7th Street<br>Suite 4-600<br>San Francisco, CA 94103-6705<br>415/437-7820<br>http://rates.psc.gov/fms/dca/western.html |

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| Office | Address |
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| Federal Audit Clearinghouse<br>(A-133 Audit Reports) | Federal Audit Clearinghouse<br>1201 E 10th Street<br>Jeffersonville, IN 47132<br><br>Questions:<br>1-800-253-0696<br>http://harvester.census.gov/sac |

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