NIH GRANTS
Policy Statement

(Revised December 1, 2003)

U.S. Department of Health and Human Services
Public Health Service
National Institutes of Health

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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 from the NIH home page at http://grants.nih.gov/grants/policy/policy.htm#gps.

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 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; outlines the grant application and review processes; and explains the various resources available to those interested in the NIH grants process.

- *Part II: Terms and Conditions of NIH Grant Awards.* Part II includes generally applicable terms and conditions. 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. These requirements, in separate sections, pertain to construction grants, research training grants and fellowships, 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 (or on behalf of) Federal employees, grants to for-profit organizations, and research patient care activities.

- *Part III: Points of Contact.* Part III lists pertinent offices and officials with their addresses and telephone numbers.

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" 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 with an effective date of March 1, 2001. This revision of the NIHGPS, which is an update of the 2001 publication, has an effective date of December 1, 2003. It applies to all NIH grants and cooperative agreements for budget periods beginning on or after December 1, 2003. It remains largely unchanged; however, 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 March 2001 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 March 2001 NIHGPS is included in the *NIH Guide for Grants and Contracts* notice announcing the reissuance of the NIHGPS.

ADDITIONAL INFORMATION

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.

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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; outlines the grant application and review processes; and explains the various resources available to those interested in the NIH grants process.

GLOSSARY

The glossary lists commonly used acronyms and other abbreviations used in the NIHGPS.[1] The glossary also defines terms commonly used throughout the NIHGPS. The definitions may be amplified and additional definitions may be found in other sections of this document and in source documents, such as applicable statutes, grants administration regulations, and OMB circulars.

Abbreviations

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
AOO	Authorized Organizational Official
APAC	Annual Payback Activities Certification
AREA	Academic Research and Enhancement Award
ASHRAE	American Society of Heating, Refrigeration and Air Conditioning Engineers
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CGMO	Chief Grants Management Officer
CMS	Centers for Medicare and Medicaid Services
CoC	Certificate of Confidentiality

[1] 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.

COR	Career Opportunities in Research Education and Training Program
CRISP	Computer Retrieval of Information on Scientific Projects
CSR	Center for Scientific Review
DAB	Departmental Appeals Board
DCA	Division of Cost Allocation, HHS
DEA	Drug Enforcement Administration
DEOIR	Division of Extramural Outreach and Information Resources, NIH
DES	Department of Engineering Services, NIH
DFAS	Division of Financial Advisory Services, NIH
DoC	Department of Commerce
DoD	Department of Defense
DoL	Department of Labor
DPM	Division of Payment Management, HHS
DSMB	Data and Safety Monitoring Board
EA	Expanded Authorities
EO	Executive Order
eRA	Electronic Research Administration
F&A	Facilities and Administrative (costs)
FAC	Federal Audit Clearinghouse
FAR	Federal Acquisition Regulation
FCTR	Federal Cash Transactions Report (SF 272)
FDA	Food and Drug Administration
FDP	Federal Demonstration Partnership
FEMA	Federal Emergency Management Agency
FIC	Fogarty International Center
FICA	Federal Insurance Contributions Act
FOI	Freedom of Information
FOIA	Freedom of Information Act
FSR	Financial Status Report (SF 269 or 269A)
FTR	Federal Travel Regulation
FWA	Federal-Wide Assurance
GCRC	General Clinical Research Centers

GMO	Grants Management Officer
GMS	Grants Management Specialist
GMP	Guaranteed Maximum Price
GPO	Government Printing Office
GSA	General Services Administration
hESC	Human Embryonic Stem Cells
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
HVAC	Heating, Ventilating, and Air Conditioning
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IC	Institute or Center
IDE	Investigational Device Exception
IHS	Indian Health Service
IND	Investigational New Drug
IPA	Intergovernmental Personnel Act
IR&D	Independent Research and Development
IRB	Institutional Review Board
IRG	Initial Review Group
IRS	Internal Revenue Service
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
MPA	Multiple Project Assurance
NCRR	National Center for Research Resources
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

NGA	Notice of Grant Award
NHSC	National Health Service Corps
NICHD	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
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
NRFA	Notice of Research Fellowship Award
NTIS	National Technical Information Service
OBA	Office of Biotechnology Activities, NIH
OCR	Office for Civil Rights, HHS
OER	Office of Extramural Research, NIH
OFCCP	Office of Federal Contract Compliance Programs, DoL
OFM	Office of Financial Management, NIH
OHRP	Office for Human Research Protections, HHS
OIG	Office of the Inspector General
OLAW	Office of Laboratory Animal Welfare, NIH
OMB	Office of Management and Budget
ONR	Office of Naval Research
OPERA	Office of Policy for Extramural Research Administration, NIH
OPHS	Office of Public Health and Science
ORI	Office of Research Integrity, HHS
PA	Program Announcement
PD	Program Director/Project Director
PHS	Public Health Service
PI	Principal Investigator
P.L.	Public Law
PMS	Payment Management System, HHS
PO	Program Official

PSC	Payback Service Center, NIH
R&D	Research and Development
RFA	Request For Applications
RFP	Request For Proposals
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
SF	Standard Form
SII	Successor-In-Interest
SNAP	Streamlined Non-competing Award Process
SO	Signing Official
SPOC	State Single Point of Contact
SRA	Scientific Review Administrator
SRG	Scientific Review Group
STTR	Small Business Technology Transfer Program
U.S.C.	United States Code
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

Definitions of Terms

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. Major A&R (including modernization, remodeling, or improvement) of an existing building is permitted under an NIH grant only when the authorizing statute for the program specifically allows that activity. (See "Allowability of Costs/Activities—Selected Items of Cost—Alteration and Renovation" and "Allowability of Costs/Activities—Selected Items of Cost—Construction.")
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 and Review Processes" for detailed information about the application process, including an explanation of the types of applications.)
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 NGA 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.
authorized organizational official	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 official is equivalent to the SO in NIH's eRA Commons.
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 office	The NIH IC responsible for the award, administration, and monitoring of particular grants.
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.")
clinical research	Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies that use human tissues that cannot be linked to a living individual. Studies falling under 45 CFR 46.101(a) (4) are not considered clinical research for purposes of this definition.
clinical trial	A 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. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g. 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety. Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use. Phase IV. Studies done 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.

competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a competing continuation award.
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. (See "Consortium Agreements" in Part II, Subpart B.)
contract under a grant	A written agreement between a grantee and a third party to acquire routine goods or services.
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. Consultants also include firms that provide professional advice or services. (See "Allowability of Costs/Activities—Selected Items of Cost—Consultant Services.")
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.
co-investigator	An individual involved with the 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 "key personnel." The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities as specified in the NIHGPS.
cost overrun	Any amount charged in excess of the Federal share of costs for the project period (competitive segment).
cost sharing	See "matching or cost sharing" in this section.
direct costs	Costs that can be specifically identified with a particular project or activity.
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.

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.
expanded authorities	Operating authorities provided to grantees that waive the requirement for NIH prior approval for specified actions (see "Administrative Requirements—Changes in Project and Budget—Expanded Authorities").
facilities and administrative costs	Costs that are incurred by a grantee for common or joint objectives and 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.
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.
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.")

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 PI.
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. Such organizations also are referred to as "commercial organizations."
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.
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 NGA. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.
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.
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.

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 "Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects.")
indirect costs	See "facilities and administrative costs."
Institute or Center	The NIH organizational component responsible for a particular grant program or set of activities. The terms "NIH IC" or "awarding office" 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. In the latter case, the terms refer specifically to the designated GMO.
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 is 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 "Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages.")
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.
key personnel	The 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 key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. "Zero percent" effort or "as needed" is not an acceptable level of involvement for key personnel.

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 law, regulation, or administrative decision of an NIH IC. Costs used to satisfy matching or cost-sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.
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.
new investigator	An individual who has not previously served as a PI on any PHS-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory development grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research careers ((K01, K08, and K12). Current or past recipients of Independent Scientist and other non-mentored career awards (K02 and K04) are not considered "new investigators."
Notice of Grant Award	The legally binding document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.
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 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.

Phase III clinical trial	As defined by NIH, a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included. (See "clinical trial.")
Principal Investigator/ Program Director/Project Director	An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity.
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").
priority score	A numerical rating of an application that reflects the scientific merit of the proposed research relative to stated evaluation criteria.
profit	See "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 income	Gross income earned by a grantee 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	The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.
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.

project period	The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a competing continuation award, and non-competing 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 "grantee."
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 misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. 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. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.
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 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 preestablished 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.
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—Ethical and Safe Conduct in Science and Organizational Operations—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 NGA 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.
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.
withholding of support	A decision by NIH not to make a non-competing continuation award within the current competitive segment.

THE NATIONAL INSTITUTES OF HEALTH AS A GRANT-MAKING ORGANIZATION

This section provides information about how NIH is organized to award and administer grants and describes its relationship to other organizations within HHS (or the Department) and external to HHS.

NIH, whose mission is to improve human health by increasing scientific knowledge related to disease and health, is an organizational component of HHS. 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.[2]

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 (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).[3] They provide the framework for the terms and conditions of NIH awards as specified in Part II of the NIHGPS.

NIH is organized into ICs, each with its own mission and functions, separate appropriations, and statutory authorities. The ICs that award grants 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 staff. The policies and procedures generally applicable to NIH grants are set forth in the NIHGPS.

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

[2] HHS components include SAMHSA, FDA, CDC, IHS, AHRQ, HRSA, ACF, AoA, OPHS, and CMS.

[3] 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.

set of expectations for grantee organizations. The grantee's roles and responsibilities have assumed greater importance as NIH has shifted to increased reliance on systems compliance and provided greater decision-making authority to grantees.

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 "Application and Review Processes" section in this Part. The responsibilities of other offices, such as OHRP, are described in Part II.

NIH and HHS Staff

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

- *Grants Management Officer.* The GMO whose name appears on the NGA 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.

- *Grants Management Specialist.* The GMS 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 SRAs; 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 in many of these activities.

- *Scientific Review Administrator.* SRAs 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 SRA 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 and HHS Staffs.* 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 (based on geographical location) DCA office or DFAS;[4] OIG; OHRP; OLAW; and ORI. 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.

Grantee Staff

The roles and responsibilities of grantee participants are as follows:

- *Authorized Organizational Official.* The AOO 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. 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 Implication of Application.") 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. Under NIH's eRA Commons, this individual is the SO. 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.

- *Principal Investigator.* The PI (who also may be known as the PD) is the individual, designated by the grantee, responsible for the scientific or technical aspects of the grant and for day-to-day management of the project or program. The PI is not required to be an employee of the grantee. However, because the grant, if awarded, is made to the organization, the applicant organization must have a formal written agreement with the 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 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.

  The PI is a member of the grantee team responsible for ensuring compliance with the financial and administrative aspects of the award. This individual works closely with

[4] ONR is the cognizant agency for negotiation of F&A costs for some NIH grantees.

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 the PI to maintain contact with the NIH PO with respect to the scientific aspects of the project and the GMO concerning the business and administrative aspects of the award.

NOTE: NIH staff members conduct official business only with the designated PI and AOOs.

Application and Review Processes

This subsection provides an overview of NIH's grant support mechanisms, types of entities eligible to receive grants, types of applications, types of funding opportunities, application submission (including application forms, application receipt points and deadlines, legal implication, and proprietary information), and the peer review process. It includes publications and NIH websites that can be accessed for additional information concerning the NIH grants process and programs.

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). The applicability of requirements may vary for different activity codes. Therefore, applicants should consult one or more of the information sources described in "Sources of Information about NIH's Grants Process and Programs" at the end of this section. Some of the distinctions also are significant for purposes of applying Part II of the NIHGPS.

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, hospitals, and, in this usage, also include individuals. Any special criteria for applicant eligibility or requirements concerning the qualifications of the PI or other staff or participants will be specified in the program solicitation, program guidelines, or other publicly available documents. Part II includes information on fellow and trainee eligibility.

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.

Types of Applications

In the NIH grants process, five types of applications are used most frequently. Each of the first four application types is 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.

- *Competing Continuation Application (Type 2)*—a request for funding to renew, by one or more additional budget periods, a project period that would otherwise expire.

- *Competing Supplemental Application (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. (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."]).

- *Revised (Amended) Application*—an unfunded application that the applicant has modified following initial review and resubmitted for consideration. NIH allows a maximum of two revised applications. An amended application may be submitted for any of the three preceding types of applications. However, NIH generally treats unfunded applications resubmitted under a different process or research grant mechanism than the original application (e.g., an application originally submitted as investigator-initiated and, subsequently, resubmitted in response to an RFA, or an application originally submitted as an R01 and, subsequently, resubmitted as an R21) as new applications rather than as amended applications.

- *Non-Competing Grant Progress Report (Type 5)*—a progress report and request for funding of a non-competing continuation award for the second or subsequent budget period within an approved competitive segment (see "Administrative Requirements—Monitoring—Reporting—Non-Competing Grant Progress Reports").

NIH uses the numbers shown in parentheses as prefixes to distinguish the application types and any resulting awards.

Types of Funding Opportunities

The preponderance of applications submitted to NIH under the categories of research and research training (including fellowships) are for investigator-initiated research and are considered "unsolicited" applications. NIH reviews such applications in three review cycles per

year.[5] The schedules for submission, review, and award of unsolicited applications are included in the application instructions and on the NIH home page.

All applicants are encouraged to contact the IC from which they plan to seek funding. See Part III for a list of the IC contact points. However, any applicant requesting $500,000 or more in direct costs in any year in an unsolicited application 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. This requirement applies to a single application, whether a new, competing continuation, competing supplemental, or revised (amended) grant application, under any NIH support mechanism; it also applies to a group of applications, such as those for clinical trial networks, meeting that threshold in the aggregate even if no single application in the group requests that much. Applicants that are uncertain about which IC to contact should contact the Division of Receipt and Referral, CSR (see Part III). 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 accompanying the application will be returned to the applicant without review. This policy does not apply to applications submitted in response to RFAs or other announcements that include specific budgetary limits. However, such applications must be responsive to any budgetary limits specified or NIH will return them to applicants without review.

NIH may develop areas of high priority or special research interest and use a special solicitation to stimulate submission of applications in those areas. These solicitations are published in the *NIH Guide for Grants and Contracts*, which is electronically linked to Grants.gov, a government-wide site for locating grant and cooperative agreement funding opportunities (http://www.fedgrants.gov).

NIH solicitations take one of two forms: PAs and RFAs. NIH uses PAs to describe new, continuing, or expanded program interests of an IC or to announce the availability of a new mechanism of support. PAs may be used for any support mechanism other than construction awards. Unless otherwise specified in the PA, new applications (and associated competing continuation and competing supplemental applications) submitted in response to PAs are treated as unsolicited, are subject to the common receipt dates, compete for funding with all other unsolicited applications, and are subject to the standard peer review process. 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.

An RFA is a more targeted solicitation; it may be used to solicit the following:

- Grant applications in a well-defined scientific area
- Research grant applications for a one-time competition

[5] Some ICs review applications for Institutional National Research Service Awards (T32) only once a year. See the Appendix in Part II of the NIHGPS.

- Construction grant applications
- Applications for cooperative agreements.

RFAs are stand-alone solicitations, and each will provide sufficient information to allow prospective applicants to determine whether to apply. That information includes the amount of funding available, the number of awards anticipated, whether cost sharing is required, the deadline date for receipt of applications, and other information describing the nature of the effort desired and the obligations of recipients. For cooperative agreements, the RFA will describe the responsibilities and obligations of NIH and awardees as well as joint responsibilities and obligations.

Application Submission

To be considered for support, an applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates. Information to be submitted typically includes a project description, budget and budget justification, biographical sketches of key personnel, and other information specified in the application instructions, in the solicitation, 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. 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.

Application Forms

Exhibit 1 lists the required application forms, which vary by support mechanism. These forms and associated instructions are available electronically on the NIH home page (http://grants.nih.gov/grants/forms.htm). Questions about application forms and instructions may be directed to DEOIR, OER, NIH by telephone at 301-435-0714 or by e-mail at GrantsInfo@nih.gov (see Part III). Certain forms (rather than a complete application kit) are available electronically on the NIH home page (http://grants.nih.gov/grants/forms.htm).

Exhibit 1. Required Forms for Competing Applications		
Application title	**Form number**	**Use**
Application for a Public Health Service Grant	PHS 398	Research project grants and cooperative agreements, program projects, centers, K awards, Kirschstein-NRSA institutional research training grants, conference grants, and SBIR and STTR grants (see Section VI of the instructions)
Application for Ruth L. Kirschstein National Research Service Award Individual Fellowship	PHS 416-1	Kirschstein-NRSA fellowships
Public Health Service Grant Application for Use by: State and Local Government Applicants and Nongovernmental Applicants for Health Services Projects	PHS 5161-1, with budget and assurances applicable to nonconstruction (424-A and 424-B) or construction (424-C and 424-D)	State, local, and Indian tribal governmental applicants for all types of grants, and nongovernmental applicants for construction grants

Application Receipt Points and Deadlines

All competing applications, whether solicited or unsolicited, are required to be sent or delivered via the USPS or a courier delivery service, in the number of copies specified in the application instructions or solicitation, to the central NIH receipt point:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive, MSC-7710
Bethesda, MD 20892-7710 (zip code for applications sent by USPS regular or Express mail)
Bethesda, MD 20817 (zip code for applications sent using a courier service)

Preaddressed mailing labels are included with the application forms.

CSR will not accept applications delivered by individuals.

Applicants responding to RFAs should submit copies of their application concurrently to CSR and the soliciting IC.

An unsolicited application will be considered to be on time for a particular review cycle if it is received by or mailed on or before the published receipt date for that cycle and a proof of mailing is provided. If the receipt date falls on a weekend or a Federal holiday, the date for receipt/mailing is extended to the next business day.

An application submitted in response to an RFA or a PA but received after the deadline date (if one is specified in the RFA or PA) may be accepted only if it carries a legible proof-of-mailing date assigned by the carrier and that date is no later than 1 week prior to the deadline date. This

applies only to PAs with specific, published receipt dates, i.e., dates other than the standard ones used for unsolicited applications. For PAs using the standard receipt dates, the rules for unsolicited applications apply as described above.

The established receipt or deadline date will be waived only in extenuating circumstances. A request for a waiver must accompany the application and must explain the basis for requesting a waiver. A waiver will not be considered before the application is received. Only CSR has the authority to waive an established receipt date.

Legal Implication of Application

The signature of an AOO 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 the accuracy, validity, and conformity with the most current organizational guidelines of all the administrative, fiscal, and scientific information in the application, including the F&A cost (indirect cost) rate. The AOO's signature further certifies that the applicant organization will be 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 directly from NIH, indirectly under a contract or consortium agreement, 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.

The HHS OIG maintains a post office box and a toll-free hot line 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 hot line are included in Part III. Anyone who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to NIH grants or grant funds is encouraged to report this information to the OIG in writing or to the OIG hot line. 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. This includes 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).

Part II of the NIHGPS 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. The

Federal government may pursue civil or criminal action under a variety of statutes and regulations.

The Program Fraud and 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 persons who knowingly make false, fictitious, or misleading claims to the Federal government for money, including money representing grants, loans, or benefits. A civil penalty of not more than $5,000 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 at 45 CFR Part 79 specify the process for imposing civil penalties and assessments, including hearing and appeal rights.

The Criminal False Claims Act, 18 U.S.C. 287 and 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 carry a maximum sentence of 5 years imprisonment and a fine of $250,000.

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 "false claim" is 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 false claim.

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

Confidentiality of Information (Proprietary 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 PHS 398 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, which are discussed in "Public Policy Requirements and Objectives" in Part II. However, if a grant is awarded as a result of or in connection with an application, the Federal government shall have 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.

The Peer Review Process

Competing applications for NIH grants and cooperative agreements, including those for competing continuations and competing supplements, are subject to peer review as required by sections 406 and 492 of the PHS Act or by NIH policy. 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 and National Advisory Council/Board review. 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 the following websites: http://www.csr.nih.gov and http://grants.nih.gov/grants/peer/peer.htm. Information also is available by e-mail at GrantsInfo@nih.gov, or by calling, writing, or faxing a request to CSR (see Part III).

Initial Review

Responsibilities

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 solicitation 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 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 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 SRAs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRA 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 scientists actively engaged in research. NIH's conflict-of-interest and confidentiality of information policies for reviewers are intended to ensure an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Within 6 to 8 weeks following the established application receipt date, applicants are notified that the application has been received and are advised of the SRA, SRG, and IC assignments. At this time, applicants may request reconsideration of the SRG and IC assignment. Once the assignment process is completed, the SRA is the contact for all communication with the applicant until the conclusion of the SRG meeting. An applicant may withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PI and an AOO. If an application is withdrawn before it enters the review process, CSR will return the application to the applicant. Applications withdrawn by the applicant after the beginning of the formal review may be destroyed by NIH or returned to the applicant at NIH's discretion.

In preparation for the initial review, SRAs review applications to determine whether they are complete, conform to administrative requirements, and contain the information necessary for a detailed review. For each reviewable application, they then assign (from among the standing and temporary members) reviewers to write a critique of the application and readers to be prepared to discuss the application in detail.

Following the initial review, the SRA prepares a summary statement for each application 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 priority score. Summary statements are then provided to the IC's program staff and the PI.

Review Criteria

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, and enhance health. Reviewers judge the likelihood that the proposed research will have a substantial impact on the pursuit of NIH's research goals by addressing, in their written comments about the application, the following criteria:

- *Significance.* Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

- *Approach.* Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

- *Innovation.* Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing models or develop new methodologies or technologies?

- *Investigator.* Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PI and other researchers (if any)?

- *Environment.* Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of organizational support?

All of the criteria, weighted as appropriate for each application, will be considered when assigning the overall score. An application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out work that, by its nature, is not innovative but is essential to move a field forward.

Although the review criteria are intended for use primarily with unsolicited research project grant applications (e.g., R01 and P01), including those in response to PAs, to the extent reasonable, the criteria also will form the basis of the review of solicited applications and 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 specific criteria as stated in RFAs or PAs.

In addition to the above criteria, in accordance with NIH policy, all applications will be reviewed with respect to the following:

- Adequacy of plans to include both genders, members of minority groups, children, and their subgroups, as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects also will be evaluated.

- Reasonableness of the proposed budget and duration in relation to the proposed research.

- Adequacy of the proposed protection for humans, animals, or the environment to the extent they may be adversely affected by the project proposed in the application.

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 review of the summary statement, they believe the review process was procedurally flawed. This appeal process is not intended to deal with differences of scientific opinion between or among 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 who will attempt to resolve the applicant's concerns. If, after discussion with the PO, the applicant still has concerns, the AOO 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 SRA 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 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 SRA 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.

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 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.

Disposition of Applications

All incomplete applications, non-compliant modular applications, and applications determined to be nonresponsive to solicitation requirements will be returned to the applicant by CSR or by the IC referral office without further action. The applicant may resubmit a changed or complete version of an unsolicited application for consideration in the next review cycle.

Following the initial review, the PI will receive a copy of the summary statement and will be advised by letter from the responsible IC whether the application has been recommended for further consideration by the Council.

The IC Director or designee is the official that has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit up to two revised versions of the application for review in a future cycle(s).

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 Part II. 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.

Sources of Information about NIH's Grants Process and Programs

NIH maintains a number of information resources about its grant programs and activities that can be accessed through OER's home page. Some are descriptive materials that enable interested parties to learn about NIH grant initiatives, funding opportunities, and proposed and actual policy changes. Others provide historical data. This information is updated annually or as needed. The NIH website address for these materials and other grant-related materials is http://grants.nih.gov/grants/oer.htm (a more specific address may be provided below). In addition, these materials may be requested by e-mail from GrantsInfo@nih.gov or by telephone at 301-435-0714 (see Part III).

The information resources include the following:

- *NIH Extramural Programs.* A compendium of the scientific programs of the NIH components that award grants, cooperative agreements, and contracts. It indicates current areas of research emphasis, highlights special interests of each IC, and identifies specific NIH offices to be contacted for further information about particular programs, policies, and procedures. The website address is http://grants.nih.gov/grants/oer.htm.

- *NIH Guide for Grants and Contracts.* A publication that announces new programs and policies, including program announcements, RFAs, and RFPs. The website address for the *NIH Guide for Grants and Contracts* is http://grants.nih.gov/grants/guide/index.htm. The NIH Guide also is available on a subscription basis. For subscription instructions, see http://grants.nih.gov/grants/guide/listserv.htm.

- *NIH Electronic Research Administration Commons.* The NIH eRA Commons facilitates research administration between, NIH, grantee organizations, and the public by providing the capability for an electronic exchange of information. The eRA Commons is divided into both unrestricted and restricted portions that provide for public and confidential information, respectively. For additional information, see https://commons.era.nih.gov/commons/.

- *Grants.gov.* An Internet site that will provide a simple, unified "storefront" for all customers of Federal grants to electronically find opportunities, apply, and manage grants. It will facilitate the quality, coordination, effectiveness, and efficiency of operations for grant-makers and grantees. For additional information, see http://www.fedgrants.gov.

- *Research Grants.* A compendium of information that includes data on NIH research grant awards organized in a variety of ways. The website address is http://grants.nih.gov/grants/award/award.htm.

- *Computer Retrieval of Information on Scientific Projects.* CRISP is an online system (http://www.crisp.cit.nih.gov) available to the public that is updated quarterly and provides a brief description of and administrative data on each NIH-funded research project.

- *Program Guidelines*. Publications that include detailed policy and procedural information applicable to specific programs/activities. NIH-wide program guidelines are published initially in the *NIH Guide for Grants and Contracts* (see above) and also are accessible by title at http://grants.nih.gov/grants/documentindex.htm. The SBIR/STTR Phase I grant guidelines are available at NIH's "Small Business Funding Opportunities" site (http://grants.nih.gov/grants/funding/sbir.htm). IC home pages also should be consulted for IC-specific guidelines (see Part III).

Each IC also maintains its own home page accessible through the NIH home page "Institutes and Offices" submenu (also see Part III for website addresses).

Part II: Terms and Conditions of NIH Grant Awards

Subpart A: General

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 Grant Progress Reports").

Just-in-Time Procedures

NIH uses just-in-time procedures for certain programs and award mechanisms. These procedures call for limited information (e.g., a budget justification and a biographical sketch) to be submitted with investigator-initiated applications and allow for a possible NIH request for additional information, including information concerning other support, when the application is under consideration for funding. Just-in-time procedures also allow an applicant to defer 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 until after completion of the peer review and just prior to funding. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

Information on other support will be requested as part of the just-in-time procedures. 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, 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 PI at the time of award.

- Only funds necessary to the approved project are included in the award.

For modular applications, the applicant is not required to submit detailed budget information in the application. In lieu of the standard budget forms, the applicant requests total direct costs for each year of support requested. The request must be accompanied by budget narrative for all personnel (by position, title, and level of effort), including consultants and "to be appointed" positions, and, when applicable, for consortium/contractual costs. NIH will request additional budget information in exceptional circumstances only. Other support information will be requested only for modular applications likely to result in an award. (See Subpart B of this part for more detailed coverage of modular applications and awards.)

Funding Principles

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. NIH also has adopted the following core funding principles specifically for research project grants:

- NIH generally will award non-competing continuation research project grants at committed levels.

- When determining commitments for future years, NIH will consider stability of support for investigators, optimum portfolio balance, and opportunities to address emerging problems.

Eligibility

NIH awards may be made only to eligible applicants. Continued funding is dependent on the grantee's maintaining eligibility. In general, domestic or foreign, public or private, non-profit or

for-profit organizations are eligible to receive NIH grants. However, on the basis of statutory, regulatory, or published policy limitations, under certain programs or types of awards, NIH may limit eligibility to, or exclude from eligibility, classes or types of entities. Examples are limitations on the participation of foreign entities, and programs under which only small businesses are eligible applicants. The determination of eligibility includes verification of the applicant's status. The applicant may be required to provide proof of its status by submitting documentation; otherwise the AOO'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 PI in the project, and the 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.

The GMO also will verify whether the applicant, proposed PI, or other key personnel are debarred or suspended from participation in Federal assistance programs (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations" for certification requirements).

Generally, PIs and other personnel supported by NIH research grants 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 PA or RFA. 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 K 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" in Subpart B of this part of the NIHGPS.

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.

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 "Cost Considerations."

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.

OVERVIEW OF TERMS AND CONDITIONS

The remainder of Part II serves as 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 includes those terms and conditions that apply, in general, to NIH awards. Subpart B either expands on Subpart A 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. In addition to the requirements in the NIHGPS, some of which repeat or highlight requirements found in the following, NIH grants are subject to all of the applicable requirements of the following:

- Authorizing program legislation
- Program regulations, including those in 42 CFR Part 52
- Other statutory requirements, such as those included in appropriations acts

- HHS requirements in 45 CFR Part 74 or 45 CFR Part 92, as appropriate for the type of recipient organization and the type of activity (e.g., research).

Notice of requirements not specified in the NIHGPS generally will be provided in the NGA, 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 written in "plain language" and is meant to be 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 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.

PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

This section addresses public policy requirements and objectives 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 HHS's annual appropriations acts 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 since they have been included in the appropriations acts for several years without change, but those requirements may be changed or other requirements may be added in the future.

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 AOO on

the application certifies that the organization complies, or intends to comply, with all applicable certifications and assurances referenced (and, in some cases, included) in the application instructions.

Instructions for applications submitted on the PHS 398 include the following topics, which also are discussed in this section of the NIHGPS:

- Debarment and Suspension (specific certification language included in application instructions)
- Drug-Free Workplace
- Lobbying (specific certification language included in application instructions)
- Financial Conflict of Interest
- Research Misconduct
- Nondelinquency on Federal Debt
- Human Embryonic Stem Cell Research
- Human Subjects
- Research on Transplantation of Fetal Tissue
- Recombinant DNA Molecules and Human Gene Transfer Research
- Vertebrate Animals
- Women and Minority Inclusion Policy
- Inclusion of Children Policy
- Age Discrimination
- Civil Rights
- Sex Discrimination
- Handicapped Individuals.

Public policy requirements under Kirschstein-NRSA individual fellowships are specified in the application instructions for the PHS 416-1 and are discussed in "Ruth L. Kirschstein National Research Service Awards—Individual Fellowships" in Subpart B of this part.

As noted in this section, some certifications and assurances may require 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 "Human

Subjects" and "Civil Rights"), the absence or inadequacy of which may delay an award or make an applicant ineligible for award.

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

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 2 contains information to help the grantee determine what public policy requirements and objectives 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" 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 public policy requirement normally would apply. However, even if the exhibit indicates that a requirement is not applicable that public policy 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 2 also indicates where, in the NIHGPS, the individual public policy requirements and objectives are covered in more detail. The grantee should consult the governing statute, regulations, or other cited policies or documents for complete information.

Exhibit 2. Public Policy Requirements and Objectives				
Requirement or objective	**Grantee**	**Consortium participant**	**Contractor under grant (routine goods/services)***	**NIHGPS section for additional information**
Acknowledgment of Federal Funding	Y	Y	NA	Availability of Information Ruth L. Kirschstein National Research Service Awards
Age Discrimination Act of 1975	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Civil Rights Grants to Foreign Institutions, International Organizations and Domestic Grants with Foreign Components (hereafter, Grants to Foreign Institutions)
Animal Welfare	Y	Y	Y	Animal Welfare Ruth L. Kirschstein National Research Service Awards Grants to Foreign Institutions
Ban on Human Embryo Research and Cloning	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients or Recipients of Services (hereafter, Requirements Affecting the Rights and Welfare of Individuals)
Certificates of Confidentiality	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals
Civil Rights Act of 1964 (Title VI)	Y (NA* to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Civil Rights Grants to Foreign Institutions
Confidentiality of Patient Records	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals
Controlled Substances	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals
Data and Safety Monitoring	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals Ruth L. Kirschstein National Research Service Awards
Debarment and Suspension	Y (NA to certain foreign organizations)	Y (NA to certain foreign organizations)	If contract equals or exceeds $100,000 (NA to certain foreign organizations)	Ethical and Safe Conduct in Science and Organizational Operations Grants to Foreign Institutions

Exhibit 2. Public Policy Requirements and Objectives				
Requirement or objective	**Grantee**	**Consortium participant**	**Contractor under grant (routine goods/services)***	**NIHGPS section for additional information**
Drug-Free Workplace	Y	NA	NA	Ethical and Safe Conduct in Science and Organizational Operations Grants to Foreign Institutions
Education Amendments of 1972 (Title IX)	Y (NA to foreign and international organizations	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Civil Rights Grants to Foreign Institutions
Elimination of Architectural Barriers to the Handicapped	Y	NA	Y	Construction Grants
Financial Conflict of Interest	Y (NA to Phase I of the SBIR/STTR programs and to Federal institutions)	Y	NA	Ethical and Safe Conduct in Science and Organizational Operations Grants to Federal Institutions and Payments to (or on behalf of) Federal Employees under Grants
Flood Insurance	Y	NA	NA	Construction Grants
Freedom of Information Act	Y (Applies to certain research data produced by specified types of grantees; NA to commercial organizations)	Y (Applies to certain research data produced by specified types of grantees; NA to commercial organizations)	Y Applies to certain research data produced by specified types of entities; NA to commercial organizations)	Availability of Information
Additional Health and Safety Regulations and Guidelines	Y	Y	Apply as required by Federal, State or local regulations	Ethical and Safe Conduct in Science and Organizational Operations
Health Insurance Portability and Accountability Act (HIPAA)	Y (if a covered entity)	Y (if a covered entity)	Y (if a covered entity)	Requirements Affecting the Rights and Welfare of Individuals
Historic Properties/ Archeological Sites	Y	NA	Y	Construction Grants
Human Embryonic Stem Cell Research	Y	Y	Y	Ethical and Safe Conduct in Science and Organizational Operations Ruth L. Kirschstein National Research Service Awards

Exhibit 2. Public Policy Requirements and Objectives				
Requirement or objective	**Grantee**	**Consortium participant**	**Contractor under grant (routine goods/services)***	**NIHGPS section for additional information**
Human Subjects	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals Ruth L. Kirschstein National Research Service Awards Grants to Foreign Institutions
Inclusion of Children as Subjects in Clinical Research	Y	Y	NA	Requirements for Inclusiveness in Research Design Ruth L. Kirschstein National Research Service Awards Grants to Foreign Institutions
Inclusion of Women/Minorities as Subjects in Clinical Research	Y	Y	NA	Requirements for Inclusiveness in Research Design Ruth L. Kirschstein National Research Service Awards Grants to Foreign Institutions
Intergovernmental Review under EO 12372	Y	NA	NA	Construction Grants
Investigational New Drug Applications/ Investigational Device Exceptions	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals
Labor Standards under Federally Assisted Construction	Y	NA	Y	Construction Grants
Limited English Proficiency	Y	Y	NA	Civil Rights
Limitation on Use of Funds for Promotion or Legalization of Controlled Substances	Y	Y	Y	Ethical and Safe Conduct in Science and Organizational Operations
Lobbying	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	Ethical and Safe Conduct in Science and Organizational Operations
Metric System	Y	Y	Y	Other Public Policy Requirements and Objectives Construction Grants
Military Recruiting and ROTC Program Access to Institutions of Higher Education	Y	Y	Y	Other Public Policy Requirements and Objectives

Exhibit 2. Public Policy Requirements and Objectives				
Requirement or objective	**Grantee**	**Consortium participant**	**Contractor under grant (routine goods/services)***	**NIHGPS section for additional information**
National Environmental Policy Act of 1969	Y	NA	NA	Construction Grants
Nondelinquency on Federal Debt	Y	Y	NA	Ethical and Safe Conduct in Science and Organizational Operations Grants to Foreign Institutions
Preservation of Open Competition and Government Neutrality Toward Government Contractors' Labor Relations on Federal and Federally Funded Construction Projects	Y	NA	NA	Construction Grants
Privacy Act	Y Applies to covered material in NIH's possession	Y Applies to covered material in NIH's possession	Y Applies to covered material in NIH's possession	Availability of Information
Pro-Children Act of 1994	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals
Program Fraud and Civil Remedies and False Claims Acts	Y	Y	NA	Application and Review Processes—Legal Implication of Application
Protection of Research Subjects' Identity	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals
Public Disclosure	Y	NA	NA	Construction Grants
Public Health Security and Bioterrorism Preparedness and Response Act	Y	Y	Y	Ethical and Safe Conduct in Science and Organizational Operations
Recombinant DNA Molecules and Human Gene Transfer Research	Y	Y	Y	Ethical and Safe Conduct in Science and Organizational Operations Ruth L. Kirschstein National Research Service Awards
Rehabilitation Act of 1973 (section 504)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Civil Rights Grants to Foreign Institutions

Exhibit 2. Public Policy Requirements and Objectives				
Requirement or objective	**Grantee**	**Consortium participant**	**Contractor under grant (routine goods/services)***	**NIHGPS section for additional information**
Research Misconduct	Y	Y	NA	Ethical and Safe Conduct in Science and Organizational Operations Grants to Foreign Institutions
Research on Human Fetal Tissue	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals
Research on Transplantation of Fetal Tissue	Y	Y	Y	Requirements Affecting the Rights and Welfare of Individuals
Restriction on Abortions	Y	Y	Y	Ethical and Safe Conduct in Science and Organizational Operations
Restriction on Distribution of Sterile Needles	Y	Y	Y	Ethical and Safe Conduct in Science and Organizational Operations
Seat Belt Use	Y	NA	NA	Ethical and Safe Conduct in Science and Organizational Operations
Smoke-Free Workplace	Y	NA	NA	Ethical and Safe Conduct in Science and Organizational Operations
Standards of Conduct	Y	NA	NA	Ethical and Safe Conduct in Science and Organizational Operations
Uniform Relocation Assistance and Real Property Acquisition Policies Act	Y	NA	NA	Construction Grants
USA PATRIOT Act	Y	Y	Y	Ethical and Safe Conduct in Science and Organizational Operations
*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.				

Ethical and Safe Conduct in Science and Organizational Operations

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 with whom they may collaborate, and that limit the potential for research results to be tainted by possible personal 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.

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 CGMOs is available at http://grants.nih.gov/grants/stafflist_gmos.htm.) If a suspension or separation action is taken by a grantee against a PI or other 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."

Financial Conflict of Interest

NIH requires grantees and investigators 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." That subpart promotes objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an investigator. These requirements do not apply to Phase I of the SBIR/STTR programs.

The signature of the AOO on the face page of the application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F. Under those requirements the organization must do the following:

- Have 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
- Before spending any NIH funds awarded under a new award, inform the CGMO of the existence of any conflicting financial interests it identified of the type covered by 42 CFR 50.605
- When informing the CGMO that a financial conflict of interest has been identified, ensure that the interest has been addressed in accordance with the regulations by indicating whether the conflict has either been managed, reduced, or eliminated
- Continue to make similar reports on subsequently identified conflicts within 60 days of identifying them
- Make additional information available to NIH, upon request, as to how it handled conflicting interests in accordance with the regulations.

As described in the regulations, examples of how financial conflicts of interest might be addressed include 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 the consortium participant's employees will be subject to the financial conflict of interest requirements of the consortium participant or to those of the grantee (see "Consortium Agreements" in Subpart B of this part).

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—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects").

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.

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 website at http://grants.nih.gov/grants/policy/coi/nih_review.htm.

Debarment and Suspension

HHS regulations published in 45 CFR Part 76 implement the government-wide debarment and suspension system for HHS' non-procurement transactions. "Non-procurement transactions" include grants, cooperative agreements, scholarships, fellowships, and loans. Accordingly, applicants for NIH grants ("primary covered transactions"), including applicants for Kirschstein-NRSA individual fellowships, are required to certify[6] that, to the best of their knowledge and belief, they and their principals (including PIs and other key personnel)

- are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
- have not, within the 3-year period preceding the application, been convicted of, or had a civil judgment rendered against them for
  - committing fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction;
  - violating a Federal or State antitrust statute;
  - embezzlement, theft, forgery, bribery, falsification or destruction of records; or

[6] This certification is accomplished by the signature of the AOO on the application. States need only certify as to their principals.

- making false statements or receiving stolen property;

- are not presently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated above; and

- have not, within a 3-year period preceding the application, had any public transaction (Federal, State, or local) terminated for cause or default.

If the applicant is unable to certify to these statements, it must, nonetheless, submit the certification and attach an explanation. The inability to certify does not automatically disqualify an organization from receiving an NIH award; however, failure to submit the required certification or the necessary explanation will cause NIH not to make an award. Appendix A of 45 CFR Part 76 contains the full text of the instructions and the certification.

A variety of "lower-tier" transactions also are subject to the certification requirement. Contractors under grants (where the contract requires the provision of goods or services that will equal or exceed $100,000) and all consortium participants must certify that they are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal agency. Grantees also are required to obtain a certification from each trainee under a Kirschstein-NRSA institutional research training grant before their appointment. If an entity or individual is unable to certify to this effect, an explanation should be attached to its proposal or to the document that defines the legal relationship between the parties (for example, the consortium agreement).

Regardless of whether a certification is required or made, organizations or individuals that are suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants or be paid from NIH grant funds, whether under a primary or lower-tier transaction, 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.

Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the AOO 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. HHS implementing regulations are set forth in 45 CFR Part 76, "Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)."

Health and Safety Regulations and Guidelines

Public Health Security and Bioterrorism Preparedness and Response Act

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The Act was implemented, in part, through regulations published by CDC at 42 CFR 73, Select Agents and Toxins. Those regulations supersede the requirements at 42 CFR 76.2 (Interstate Shipment of Etiological Agents), which established certain shipping and handling requirements on laboratory facilities that send or receive select agents. Copies of these regulations are available from the Import Permit Program and Select Agent Program, respectively, CDC, 1600 Clifton Road, MS E-79, Atlanta, GA 30333; telephone: 404-498-2255. These regulations also are available at http://www.cdc.gov/od/ohs/biosfty/shipregs.htm.

Research involving select agents and recombinant DNA molecules also is subject to the *NIH Guidelines for Research Involving DNA Molecules* (NIH Guidelines) (see "NIH Guidelines for Research Involving DNA Molecules and Human Gene Transfer Research" in this subsection 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://www4.od.nih.gov/oba/rac/guidelines/guidelines.html.

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 subsection).

Additional Health and Safety Regulations and Guidelines

Grantees are responsible for meeting 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 1910.1030, Bloodborne pathogens; 29 CFR 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://bmbl.od.nih.gov/index.htm.

- 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 office, 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.

Limitation on Use of Funds for 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. 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 "Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Controlled Substances").

Lobbying

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 nonappropriated 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 AOO on the application serves as the required certification of compliance for the applicant organization. Disclosure reporting is addressed in "Administrative Requirements—Monitoring—Reporting."

NIH appropriated funds may not be used to pay the salary or expenses of an employee of a grantee, consortium participant, or contractor or those of an agent related to any activity designed to influence legislation or appropriations pending before Congress or any State legislature. This prohibition extends to the use of funds for publicity or propaganda purposes, including the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before Congress or a State legislature except in presentation to the Congress or State legislature itself or as part of normal, recognized legislative-executive relationships. Also see Cost Considerations—Allowability of Costs and Activities—Selected Items of Cost."

Research Misconduct

The grantee will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. Title 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science," specifies grantee responsibilities in dealing with and reporting possible research misconduct. By signing the application, the AOO certifies that the organization has established administrative policies as required by 42 CFR 50, Subpart A, and will comply with those policies and the requirements of the regulations. The regulations are available from the ORI on its home page (http://www.ori.dhhs.gov) and, in hard copy, at the address shown in Part III.

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 50.103 and 50.104. The grantee must report promptly to ORI any incident of alleged or apparent research misconduct that it judges as warranting investigation and must advise ORI of any decision to initiate an investigation. The regulations also require that the grantee submit an annual report (see "Administrative Requirements—Monitoring—Reporting").

If a misconduct investigation has been 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 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 PI or other key personnel. Examples of possible sanctions by NIH are withdrawal of approval of the PI or other 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.

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

NIH Guidelines for Research Involving Recombinant DNA Molecules and Human Gene Transfer Research

Scope and Applicability

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines) (April 2002 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://www4.od.nih.gov/oba/rac/guidelines/guidelines.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. Recombinant DNA research involving select agents also is subject to pertinent CDC and USDA regulations.[7] Specific

[7] 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.*

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.

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 establish a standing IBC. The IBC is required to review each proposed project for recombinant DNA experiments and certify 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 must be submitted to NIH's OBA (see Part III for address). At a minimum, the roster should include the names, addresses, occupations, and qualifications of the chairperson and members of the committee. The roster also should indicate which IBC members are serving as the chairperson, contact person, and, as applicable, experts in biosafety or plant, animal, or human experimentation. Section IV of the NIH Guidelines also specifies the roles and responsibilities of PIs and grantees in relation to IBCs and in other areas.

Safety and Annual Reporting

Appendix M-I-C-4 of the NIH Guidelines requires serious adverse events that are unexpected and are possibly associated with human gene transfer intervention to be reported 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.

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 AOO 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 still will take that delinquency into account when determining whether the applicant would be responsible with respect to an NIH grant, if awarded.

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 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.

NIH Guidelines for Research Using Human Embryonic Stem Cells

NIH will fund research using human pluripotent stem cells derived from human embryos (technically known as human embryonic stem cells) or human fetal tissue (technically known as human embryonic germ cells). For purposes of these NIH Guidelines, human pluripotent stem cells are cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not in themselves embryos.

NIH research funded under these Guidelines will involve human pluripotent stem cells derived: (1) from human fetal tissue or (2) from human embryos that are the result of in vitro fertilization and meet the following Presidential criteria. On August 9, 2001 at 9:00 p.m. EDT, the President announced his decision to allow Federal funds to be used for research on existing human embryonic stem cell lines as long as prior to his announcement (1) the derivation process. (which begins with removal of the inner cell mass from the blastocyst) had already been initiated and (2) the embryo from which the stem cell line was derived no longer had the possibility of development as a human being.

In addition, the President established the following criteria that must be met:

- The stem cells must have been derived from an embryo that was created for reproductive purposes.
- The embryo was no longer needed for those purposes.
- Informed consent must have been obtained for donation of the embryo.
- No financial inducements were provided for donation of the embryo.

The complete notice explaining the President's policy can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html.

In order to facilitate research using human embryonic stem cells, the NIH Human Embryonic Stem Cell Registry lists the human embryonic stem cells that meet the eligibility criteria. The laboratories or companies that provide the cells listed on the Registry must have submitted to NIH a signed assurance. Each provider must retain for submission to NIH, if necessary, written documentation to verify the statements in the signed assurance. The Registry is accessible to investigators on the NIH home page at http://escr.nih.gov/. Requests for Federal funding must cite a human embryonic stem cell line that is listed on the NIH Registry.

Although NIH withdrew those sections of the *NIH Guidelines for Research Involving Human Pluripotent Stem Cells* (http://stemcells.nih.gov/policy/guidelines.asp) that pertain to research involving human pluripotent stem cells derived from human embryos, the NIH Guidelines contain important and current information regarding specific types of research that are eligible and ineligible for NIH funding.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the *NIH Guidelines for Research Involving Human Pluripotent Stem Cells*. The review process is described at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html.

Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

Restriction on Abortion Funding

NIH funds may not be spent for an abortion.

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.

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.

Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services

Human Embryo Research, Cloning, and Transplantation

Ban on Human Embryo Research and Cloning

NIH funds may not be used to support human embryo research under any extramural award instrument. NIH funds may not be used for the creation of a human embryo for research purposes or for research in which a human embryo is destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204 and 46.207 and subsection 498(b) of the PHS Act. The term "human embryo" includes any organism not protected as a human subject under 45 CFR 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.

Research on Human Fetal Tissue

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable 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, sections 498A and 498B of the PHS Act, 42 U.S.C. 289g-1 and 298g-2, is available on the NIH website at http://grants.nih.gov/grants/guide/notice-files/not93-235.html.

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 AOO'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.

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 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 PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.
- The 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.

The AOO also is certifying that the physician's statement, the PI's statement, and the acknowledgment of the transplantation recipient will be available for audit by the HHS Secretary or designee.

Research on Transplantation of Fetal Tissue

In submitting an application to NIH, the AOO 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 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 issued a letter on November 30, 2000, indicating that it has jurisdiction over fetal cells and tissues intended for use in humans. FDA is requesting 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/cber/ltr/fetal113000.htm.

Confidentiality

NIH expects grantees and others involved in NIH grant-supported research to take appropriate actions to protect the confidentiality of information about and the privacy of individuals participating in the research. Investigators, DSMBs, IRBs, and other appropriate entities should ensure that policies and procedures are in place to protect identifying information and must oversee compliance with those policies and procedures.

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 authorization may not be compelled to disclose subjects' identities 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 website 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 office review and approval, a certificate may be issued pursuant to section 301(d).

Confidentiality of Patient Records

Section 543 of the PHS Act requires that records of substance abuse patients be kept confidential except under specified circumstances and purposes. The covered records are those that include the identity, diagnosis, prognosis, or treatment of any patient maintained in connection with any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research that is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States. This requirement is implemented in 42 CFR Part 2.

Standards for Privacy of Individually Identifiable Health Information

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 website (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 website and also at http://privacyruleandresearch.nih.gov/. That website also includes other educational materials sanctioned by OCR and the Office of the General Counsel, HHS. Additional information on the impact of the Privacy Rule on NIH processes involving the review, funding, and performance monitoring of grants can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

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.

Human Subjects

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

The Federal regulations require that each institution, domestic or foreign, "engaged" in human subjects research provide OHRP with a satisfactory Assurance of compliance with the regulations, unless the research is exempt under 45 CFR 46.101(b). An institution becomes "engaged" in human subjects research when its employees or agents (1) intervene or interact with living individuals for research purposes, or (2) obtain individually identifiable private information for research purposes (45 CFR 46.102(d) and (f)).

The HHS regulations require that departments and agencies (e.g., NIH) will conduct or support research covered by this policy only if the institution has an assurance approved by OHRP, and only if the institution has certified to NIH that the research has been reviewed and approved by an IRB provided for in the assurance and will be subject to continuing review by the IRB. Under no condition shall research covered by the regulations be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB (45 CFR 46.103(b) and (f)).

If, at the time of award, a grantee does not have an assurance approved by OHRP and certification of IRB review and approval, NIH will place a restriction on the award so that no human subjects research can be conducted or supported at that site until the assurance and certification of IRB review and approval have been obtained and accepted by NIH. The awardee institution bears ultimate responsibility for protecting human subjects under the award, including human subjects at all participating and consortium sites, and for ensuring that an Assurance

approved by OHRP and certification of IRB review and approval have been obtained before human subjects research can be conducted at each collaborating site.

For this requirement, the definitions in 45 CFR 46.102 apply as follows:

- *Human subject.* A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

- *Research.* A systematic investigation, including research, development, test, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs include research activities.

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

Assurance Requirements and Institutional Review Boards

OHRP negotiates assurances covering all of an organization's federally supported research activities involving human subjects. [8] Applicant organizations proposing to involve human subjects in nonexempt research must file (or have previously filed) a written assurance (FWA) with OHRP setting forth the commitment of the organization to establish appropriate policies and procedures for the protection of human subjects. For organizations proposing nonexempt research involving human subjects and not currently holding an approved assurance, OHRP will negotiate an FWA.

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. 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 website (http://www.hhs.gov/ohrp/).

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[8] As of February 28, 2001, OHRP no longer accepted applications for Multiple Project Assurances (MPAs) or Single Project Assurances (SPAs) limited to HHS-supported research, to special categories of research, or to individual research projects. Current MPAs will remain in effect until the designated expiration date or December 31, 2003, whichever comes first; however, MPA organizations may file a new FWA at any time prior to that date. OHRP will not accept changes to existing MPAs (except for IRB membership updates). If changes are necessary, the organization should file an FWA. Current SPAs will remain in effect through the expiration of their respective grant (or contract) award and any non-competing continuation award.

In addition to the requirement for an assurance, NIH will not award a grant for nonexempt research in which human subjects are involved unless the grantee provides a certification to NIH that the research has been approved by an appropriate IRB, consistent with 45 CFR Part 46, within 12 months before the budget period start date. IRB approval is not required before NIH peer review of an application. Rather, following peer review and notification of priority score/percentile, applicant organizations should proceed with IRB review for those applications that have not yet received IRB approval and that appear to be in a fundable range. Regardless of when the IRB review occurs, the IRB should ensure that the research described in the application is consistent with any corresponding protocols reviewed and approved by the IRB.

It is the grantee organization's responsibility to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved assurance and IRB approval of the research 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"). The list of organizations with approved assurances is available at the OHRP website (http://ohrp.osophs.dhhs.gov). 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 OHRP-approved assurance 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.

As specified in 45 CFR 46.111, the IRB review must include a determination that, for research covered by the regulations, the following conditions are met:

- The procedures to be used will minimize risks to subjects.
- Risks to subjects are reasonable in relation to expected benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable.
- Informed consent is sought from each prospective subject or the subject's legally authorized representative and is appropriately documented in accordance with, and to the extent required by, the regulation.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, the protection of privacy, and the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, people with acute or severe physical or mental illness, or people who are economically or educationally disadvantaged, appropriate additional safeguards are included in the study to protect the rights and welfare of these subjects.

If an IRB considers the impact of potential financial (or other) conflicts of interest on the research and the protection of human subjects, it should refer to the organization's policies and procedures for identifying and monitoring conflicts of interest (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Standards of Conduct—Financial Conflict of Interest").

The regulations specify additional protections for research involving human fetuses, pregnant women, and neonates (Subpart B); prisoners (Subpart C); and children (Subpart D).

OHRP also has 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 FWA preparation and negotiation 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://ohrp.osophs.dhhs.gov. OHRP also has produced a publication, available through the GPO[9], and an instructional videotape.

Education in the Protection of Human Research Participants

Before funds are awarded for competing applications involving human subjects, applicants must submit documentation that all key personnel have received training in the protection of human subjects. Key personnel include all individuals responsible for the design or conduct of the study, including key personnel of consortium participants or alternate performance sites if they are participating in research that involves human subjects. This documentation should be part of a cover letter signed by the AOO 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 key personnel should be part of the progress report submitted as a prerequisite to award. Additional information about this education requirement is available on the NIH website at: http://grants.nih.gov/grants/policy/hs_educ_faq.htm.

[9] *Protecting Human Research Subjects: Institutional Review Board Guidebook*, 1993, Stock No. 017-040-00525-3, may be ordered from the Superintendent of Documents, telephone: 202-512-1800. This Guidebook is also available from OHRP's website (http://www.hhs.gov/ohrp/irb/irb_guidebook.htm).

Data and Safety Monitoring

For all federally funded research involving human subjects, the regulations for the protection of human subjects (45 CFR 46) specify criteria for IRB approval of research and require, at 45 CFR 46.111(a)(6), that "[W]hen appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects."

NIH provides the following more specific requirements for data and safety monitoring. NIH requires oversight and monitoring of all human 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 of monitoring should be commensurate with the risks and the size 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*. The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a/an

- PI (required),
- independent individual/safety officer,
- designated medical monitor,
- internal committee or board with explicit guidelines,
- DSMB (required for multi-site trials), and
- IRB (required).

For competing research applications including clinical trials, the applicant must include a general description of the data and safety monitoring for review by the SRG. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for monitoring and how adverse events will be reported to the IRB) and, if appropriate, OBA, and FDA in accordance with IND or IDE regulations. In specific cases where the NIH awarding office is the sponsor of the test agent, i.e., the holder of the IND application, investigators must submit individual adverse event reports to the awarding office in accordance with FDA regulations.

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 office prior to the accrual of human subjects. The awarding office 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 should always be evaluated for appropriateness for the particular investigation.

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 contained in several *NIH Guide for Grants and Contracts* notices (http://grants.nih.gov/grants/guide/notice-files/not99-107.html, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html, and http://grants.nih.gov/grants/guide/notice-files/not98-084.html) and the PHS 398 instructions (http://grants.nih.gov/grants/funding/phs398/instructions2/p1_specific_instructions.htm).

Investigational New Drug Applications/Investigational Device Exceptions

To be eligible for NIH funding, all clinical research involving INDs, drugs approved for a different indication, or experimental combinations of drugs must meet FDA's IND regulations, FDA's human subjects' protection requirements, and HHS's human subjects' requirements. As provided in the FDA regulations, an IND or IDE also may apply to biologics or devices. The FDA regulations are published in 21 CFR Parts 50 and 312.

The official sponsor of the IND/IDE, whether NIH, a grantee, or a third party, is legally responsible for meeting the FDA requirements. 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 grantee is ultimately responsible to NIH for ensuring compliance with the 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 all, or 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 office within 72 hours of receiving a copy of or upon being informed of the FDA communication (through the 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 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").

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 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 AOO will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH grant should be directed to the GMO.

Animal Welfare

The *PHS Policy on Humane Care and Use of Laboratory Animals* (the Policy) requires applicants proposing to use vertebrate animals in NIH-supported activities to file a written Animal Welfare Assurance with OLAW. The Policy defines "animal" as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing, or related purposes. Under the Policy, the applicant/grantee is responsible for the humane care and treatment of animals in NIH grant-supported activities. The Policy implements and supplements the U.S. Government Principles for the Care and Utilization of Vertebrate Animals used in Testing, Research, and Training. The Policy also requires the applicant to establish appropriate policies and procedures for the humane care and use of animals, based on the Guide for the Care and Use of Laboratory Animals, and to comply with the Animal Welfare Act and its implementing regulations. This includes appointing an IACUC with specified responsibilities.

NIH will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites are operating in accordance with an approved Animal Welfare Assurance and provide verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the Policy. NIH will not make an award for research involving live vertebrate animals to an individual unless that individual is affiliated with an organization that accepts responsibility for compliance with the Policy and has filed the necessary assurance with OLAW.

Applications from organizations with approved Animal Welfare Assurances will be considered incomplete if they do not contain the information concerning the use of vertebrate animals required as part of the application's research plan (see instructions for completing the PHS 398 and PHS 416-1 for the specific points that need to be addressed). In the case of apparent or potential violation of the Policy, NIH may refer an application back to the applicant for further IACUC review.

Verification of the IACUC review may be filed at any time before award unless required earlier by the IC. Therefore, following peer review and notification of priority score/percentile, applicant organizations with approved Assurances should proceed with IACUC review for those applications that have not yet received IACUC approval and that appear to be in a fundable range. Regardless of when the review occurs, the IACUC should ensure that the research described in the application is consistent with any corresponding protocols reviewed and approved by the IACUC. If an application is selected for award and the verification of IACUC

review has not been submitted, the awarding office will contact the organization with instructions for negotiating an assurance or submitting the IACUC verification.

When organizations collaborate and multiple recognized IACUCs may be involved, only one of those IACUCs is required to review the research project or evaluate a program facility. In such cases, organizations must define their respective responsibilities to ensure compliance with the Policy. If both institutions have full Animal Welfare Assurances, they may exercise discretion in determining which IACUC will review the research protocol(s) and under which organization's program the research will be performed.

OLAW may negotiate an inter-organizational Animal Welfare Assurance when an awardee organization without an animal care and use program or IACUC will rely on the program of an organization with an assurance. Assured institutions also have the option to amend their Animal Welfare Assurances to cover performance sites without such assurances.

Foreign organizations proposing activities involving vertebrate animals are required to comply with the Policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

The Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. In addition, all organizations are required to comply, as applicable, with the Animal Welfare Act, as amended, 7 U.S.C. 2131 et seq., and other Federal statutes and regulations relating to animals.

Information about preparing and submitting Animal Welfare Assurances and copies of the Policy and other relevant materials are available from OLAW (see Part III for contact information).

Requirements for Inclusiveness in Research Design

NIH requires grant-supported research projects to be as inclusive in design as possible to extend the validity of research findings and allow for enhancement of the health status of all population groups.

Inclusion of Women and Minorities as Subjects in Clinical Research

Clinical research involving human subjects of any age must comply with 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), implementing section 492B of the PHS Act. These guidelines require that women and members of minority groups and their subpopulations (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html) be included in any NIH-supported biomedical and behavioral clinical research project involving human subjects, unless a clear and compelling rationale and justification establishes, to the satisfaction of the IC Director, that inclusion is inappropriate with respect to the health of the subjects, the purpose of the research, or other circumstances. Cost is not an acceptable reason for exclusion, except when the research would duplicate data already available from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. The guidelines should be reviewed for policy concerning

inclusion of these groups in all NIH-supported clinical trials. This policy applies to subjects of all ages.

One of the requirements of those guidelines is collecting information on racial/ethnic group in accordance with government-wide requirements to allow comparisons to other Federal databases, especially the census and national health databases. OMB Directive No. 15 (http://www.whitehouse.gov/omb/fedreg/race-ethnicity.html) defines minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all Federal reporting. 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." Reports of data on race and ethnicity shall use these categories. These categories are defined in OMB Directive 15.

Peer reviewers will evaluate proposed plans for inclusion of members of minority groups and both genders, the design of clinical trials, and recruitment and outreach as part of the scientific assessment. Failure to comply with this policy may result in NIH not making an award. Grantees are required to report annually on the enrollment of individuals by gender and racial or ethnic minority group as part of the grant progress report, including SNAP reporting (see "Administrative Requirements—Monitoring—Reporting—Non-Competing Grant Progress Reports").

Inclusion of Children as Subjects in Clinical Research

NIH has a separate policy on inclusion of children as subjects in clinical research that is similar to the policy regarding inclusion of women and minorities (http://grants.nih.gov/grants/funding/children/children.htm). All new research projects involving human subjects research must include children in the research design unless there are scientific or ethical reasons not to include them. If children will be excluded from the research, the application must present an acceptable justification for the exclusion. For the purpose of addressing the NIH policy requirement for inclusion, a child is defined as an individual under the age of 21 years.

The inclusion of children as subjects in research must comply with all applicable provisions of pertinent Federal laws and regulations, including 45 CFR Part 46. Regulatory requirements in 45 CFR 46 Subpart D address HHS protections for children who participate in research. These requirements must be addressed when "children" (persons who, under the applicable law of the jurisdiction in which the research will be conducted, have not attained the legal age for consent to treatments or procedures involved in the research) are involved as subjects in research.

This policy applies to both exempt and nonexempt research activities (see "Human Subjects" in this section); however, if the applicant claims that the proposed study meets the criteria for exemption 4 under 45 CFR Part 46, no justification for the exclusion of children is required.

Civil Rights

Before NIH may make an award to a domestic organization, the AOO must certify, by means of the signature on the application, that the organization has on file with OCR an 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, from the awarding office, the required form and instructions for completion and submission. 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.

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.

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.

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.

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 handicap, 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.

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 website at http://www.hhs.gov/ocr/lep/revisedlep.html.

Environmental Impact and Other Requirements Related to Acquisition, Alteration and Renovation, and Construction of Facilities

Public policy requirements that apply to construction activities are described in "Construction Grants—Public Policy Requirements and Objectives." Those requirements also may apply to A&R activities. A grantee undertaking an A&R project under a nonconstruction award should consult the GMO concerning potential applicability of these requirements.

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 PI, and the project description, in the CRISP system. 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 CRISP (available from the OER home page) 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.

Acknowledgment of Federal Funding

As required by HHS appropriations acts, 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.

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 and generally do not 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.

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 and competing continuations and competing supplemental 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 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.

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 PI, before the information is released. The PI will be given an opportunity to identify potentially patentable or commercially valuable information that

the PI believes should not be disclosed. After NIH consideration of the response, the PI and grantee will be informed if NIH does not agree with the PI's position. If a document contains both disclosable and nondisclosable information, the nondisclosable information will be deleted 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 website (http://www.nih.gov/icd/od/foia).

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 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 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 website 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.")

The Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a, 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 determine what information about them is maintained in Federal agencies' files (hard copy or electronic) and how it is used, to have access to such records, and to correct, amend, or request deletion of information in their records that is inaccurate, irrelevant, or outdated.

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. NIH has two Privacy Act systems of records that cover NIH grant records:

- 09-25-0036, Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement Information/Chartered Advisory Committee Information), HHS/NIH/OER and HHS/NIH/CMO

- 09-25-0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

These two systems provide guidance on requirements for the management of applicable grant records in NIH's possession and include appropriate routine uses of such information. They also include requirements for safeguarding the records and for record retention and disposal.

Parties other than PIs may request the release of Privacy Act records. Such requests are processed in the same manner as FOIA requests. 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 that individual, 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.

Other Public Policy Requirements and Objectives

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" in Subpart B of this part for requirements for metric usage in construction activities.

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

NIH is subject to section 588 of the National Defense Authorization Act of 1995, as implemented in 32 CFR Part 216, that precludes 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 may either continue the award or take an action to end the award 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 to DoD.

THE NOTICE OF GRANT AWARD

The NGA 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. An NGA is issued for the initial budget period and each subsequent budget period in the approved project period. The NGA reflects any future-year commitments. A revised NGA 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 NGA to reflect a grantee's post-award rebudgeting. Until an IC has issued an NGA for the initial award, any costs incurred by the applicant for the project are incurred at its own risk (see "Allowability of Costs/Activities—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs" for NIH policy on the allowability of pre-award costs).

The NGA 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 of the PI
- 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.

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 NGA. 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 NGA are binding on the grantee unless and until modified by a revised NGA signed by the GMO.

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 office on the basis of

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

The initial NGA 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. An NGA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NGA.

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 Grant Progress Report"). A decision to fund the next budget period will be formalized by the issuance of an NGA indicating the new budget period and the amount of new funding. The NGA 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").

Budget

Each NGA 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"). 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 Subpart B of this part as well as under other NIH programs or awards if specified in the funding opportunity announcement.

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 52.9 and 45 CFR 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.

PAYMENT

HHS grant payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, CASHLINE/ACH, or cash request, or by cash request on a reimbursement basis, as specified in the NGA and as described in this section. Payments under NIH grants generally are made as advance payments. Except as indicated in this section, NIH grant payments are made by PMS, operated by DPM, in accordance with Department of the Treasury and OMB requirements, as implemented by 45 CFR 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 contained in the *DHHS Manual for Recipients Financed under the Payment Management System* (available through the HHS website at http://www.dpm.psc.gov/doc/hhsrecmanual.pdf). Inquiries regarding payments should be directed to DPM at the address shown in Part III of the NIHGPS.

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

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.

CASHLINE/ACH

The CASHLINE/ACH method of advance payment provides for direct deposit of funds to the recipient's bank account using a touch-tone telephone to dial directly to a "voice-response" computer located at PMS. CASHLINE/ACH makes funds available the day following the request with direct deposit using the Federal Reserve Bank's ACH process.

Cash Request

Grantees not eligible for an unrestricted advance of funds by SMARTLINK II/ACH or CASHLINE/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 office. 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 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 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 office 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 office.

Interest Earned on Advances of Grant Funds

Except as provided in 45 CFR 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.

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 (EFT) capability should use an electronic medium to remit interest.

- Governmental grantees other than States. Except as provided in 45 CFR 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 92.20 and 21.

COST CONSIDERATIONS

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 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 section 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.

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 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 74.27 and 92.22:

- OMB Circular A-21—Cost Principles for Educational Institutions
- OMB Circular A-87—Cost Principles for State and Local Governments and Indian Tribal Governments
- OMB Circular A-122—Cost Principles for Non-Profit Institutions[10]
- 45 CFR Part 74, Appendix E—Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals
- 48 CFR Subpart 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 Subpart B of this part.

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

[10]Larger non-profit organizations that are specifically listed in Attachment C to OMB Circular A-122 are subject to the Federal cost principles applicable to commercial organizations (48 CFR Subpart 31.2) rather than to the cost principles for non-profit organizations.

The cost principles address four tests that NIH follows in determining 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.

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

- *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. "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. Subpart B of this part contains additional information on allowability of costs for particular types of grants, grantees, and activities.

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

Direct Costs and Facilities and Administrative Costs[11]

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). 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, therefore, 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.

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 Subpart B of this part.) 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 NGA constitutes NIH's maximum financial obligation to the grantee under that award.

Reimbursement of Facilities and Administrative Costs

NIH will not reimburse 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 or for awards under which NIH does not reimburse F&A costs.

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 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.

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[11] This term 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 functions may refer to them as "indirect costs."

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 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 costs are subject to downward adjustment if the proposal that served as the basis for the negotiation included unallowable costs.

Some award mechanisms require negotiation of project costs annually, e.g., GCRCs, 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.

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, expenditures for equipment, and subgrants and contracts in excess of $25,000. State and local governmental agencies, except State universities or hospitals, and Indian tribal governments may receive full F&A cost reimbursement under NIH Kirschstein-NRSA institutional research training grants and K awards.

- *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.

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 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 its 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.

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.

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 FSR, whether those credits accrue during or after the period of grant support. (See "Administrative Requirements—Monitoring—Reporting" and "Administrative Requirements—Closeout—Final Reports.") The NIH awarding office will notify the grantee of any additional actions that may be necessary.

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. Typically, 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 grantee foundation 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 is 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.

Allowability of Costs/Activities

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

This subsection also includes NIH-specific requirements concerning costs and activities. The allowability of costs under individual NIH awards may be subject to other requirements specified in the program legislation, regulations, or the specific terms and conditions of an award, which will take precedence over the general discussion provided here. 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 subsection, the text specifies whether the cost is usually a direct cost or an F&A cost.

Unless otherwise indicated in the NGA, 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") 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.

Selected Items of Cost

Advertising	Allowable only for recruitment of staff or trainees, 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 subsection and in the "Construction Grants" section, as applicable. Individual A&R projects exceeding $500,000 in direct costs will be subject to the requirements specified in the "Construction Grants" section. Routine maintenance and repair of the organization's physical plant or its equipment, which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this policy. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, may be considered either equipment costs or A&R costs, depending on the grantee's accounting system. A&R costs are not allowable under grants to individuals, foreign grants, and grants in support of scientific meetings (conference grants). In all other cases, these costs are allowable unless the program legislation, implementing regulations, program guidelines, or other terms and conditions of the award specifically exclude such activity. The A&R must be consistent with the following criteria and documentation requirements: ◆ The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required ◆ The A&R is essential to the purpose of the grant-supported project ◆ The space involved will be occupied by the project ◆ The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage ◆ If the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the project period. Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost. 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 office the documentation specified in "Construction Grants" for approval of A&R projects above that dollar level.

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 website: (http://www.ncrr.nih.gov/newspub/CARS.pdf) or from NCRR's Office of Science Policy and Public Liaison (telephone: 301-435-0888; e-mail: info@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. A recipient with in-house production capability must determine whether it would be more efficient and economical to use that capability or to contract for the production of an audiovisual. If an audiovisual intended for members of the general public (i.e., people who are not researchers or health professions personnel or who are not directly involved in project activities as employees, trainees, or participants such as volunteers or patients) is produced under an NIH grant-supported project, the grantee must submit two prints or tapes 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 prints or tapes are allowable project costs. Audiovisuals produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, such as the following: The production of this [type of audiovisual (motion picture, television program, etc.)] was supported by Grant No._____ from [name of NIH awarding office]. Its contents are solely the responsibility of [name of grantee organization] and do not necessarily represent the official views of [name of NIH awarding office].
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 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 Proposal Costs	Allowable as an F&A cost. See 45 CFR 74.27(b)(1) for policy for non-profit organizations covered by OMB Circular A-122.
Bonding	Allowable. See 45 CFR 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 NGA. 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 Subpart B of this part)
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 subsection).
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)" in Subpart B of this part 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 "Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements" for policies that apply to the acquisition of routine goods and services and "Consortium Agreements" in Subpart B of this part 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 NGA. 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" in Subpart B of this part).
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." 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 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.

	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 can an individual be paid as a consultant and an employee under the same NIH grant. Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be provided in writing, on a case-by-case basis, by the head of the recipient organization, consortium participant, or contractor incurring the costs, or his/her designee. 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. 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. See "Grants to Federal Institutions and Payments to (or on Behalf of) Federal Employees under Grants" in Subpart B of this part 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 nonconstruction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see "Reserve Funds" in this subsection). (See "Construction Grants—Allowable and Unallowable Costs and Activities" in Subpart B of this part concerning contingency funds under construction grants.)
Customs and Import Duties	Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (Also see "Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components—Allowable and Unallowable Costs" in Subpart B of this part 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 for payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related.
Drugs	Allowable if within the scope of an approved research project. Project funds may not be used to purchase drugs classified by FDA as "ineffective" or "possibly effective" except in approved clinical research projects or in cases where there is no alternative other than therapy with "possibly effective" drugs.

Dues or Membership Fees	Allowable as an F&A cost for organizational membership in business, professional, or technical organizations or societies. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds.
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." In accordance with the requirements of NIH appropriations acts, American-made items should be purchased to the extent possible. Funds provided under a conference grant may not be used to purchase equipment. 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 of equipment, see "Rental or Lease of Facilities and Equipment" in this subsection.
Federal (U.S. Government) Employees	See "Grants to Federal Institutions and Payments to (or on Behalf of) Federal Employees under Grants—Allowable and Unallowable Costs" 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 office.
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 subsection). 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" in this subsection. 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, Fees, and Health Insurance" in Subpart B of this part 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 subsection.

Indemnification	Allowable to the extent expressly provided in the award for indemnification against liabilities to third parties and any other loss or damage not compensated by insurance or otherwise.
Independent Research and Development Costs	Unallowable, including their proportionate share of F&A costs.
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. The cost of insuring equipment, whether purchased with project funds or furnished as federally owned property, normally should be included in F&A costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy. Health insurance for trainees and fellows is addressed in "Ruth L. Kirschstein National Research Service Awards" in Subpart B of this part.
Interest	Allowable as an F&A cost for certain assets as specified in the applicable cost principles. Unallowable for hospitals.
Invention, 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 applications, and fees paid to the U.S. Patent and Trademark Office for patent application, patent maintenance, or recordation of patent-related information. (Section Revised per 5/27/2004 NIH Guide)
Leave	Allowable for employees as a fringe benefit (see "Fringe Benefits" in this subsection). 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 Subpart B of this part 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. 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.
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. (Also see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying" and "Administrative Requirements—Monitoring—Reporting" concerning lobbying restrictions, the required certification, and reporting.)
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.
Moving	See "Recruitment Costs," "Relocation Costs," and "Transportation of Property" in this subsection.
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" in this subsection.
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. 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 competing continuation award if such costs: ◆ are necessary to conduct the project, and ◆ would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the 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. Grantees may incur pre-award costs before the beginning date of a non-competing continuation award without regard to the time parameters stated above. The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the 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.
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. Page charges for publication in professional journals are allowable if the published paper reports work supported by the grant and the charges are levied impartially on all papers published by the journal, whether or not by government-sponsored authors. The costs of reprints and publishing in other media, such as books, monographs, and pamphlets, also are allowable. 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. 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" and "Relocation Costs" in this subsection).
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 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. When there is a change in the grantee organization, the personal relocation expenses of the 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. In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. However, see "Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements" for an exception to this general rule. Rental costs under leases that create a material equity in the leased property, as defined in 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. 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. 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 office. "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 "Research Patient Care Costs" in Subpart B of this part for NIH policy concerning reimbursement of these costs. The following otherwise allowable costs are not classified as research patient care costs items of personal expense reimbursement, 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 subsection).
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 reflect no more than the percentage of time actually devoted to the NIH-funded project. As required in its annual appropriations act, NIH will not reimburse grantees for the direct salaries of individuals at a rate in excess of the level specified in the appropriations language. Direct salary is exclusive of fringe benefits and F&A costs. This salary limitation does not apply to consultant payments or to contracts for routine goods and services but it does apply to consortium participants (see "Consortium Agreements" in Subpart B of this part).

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 generally accepted practices of like organizations. Standards for payroll distribution systems are contained in the applicable cost principles (other than those for for-profit organizations). Briefly summarized, acceptable systems are as follows: ◆ Hospitals ➢ Monthly after-the-fact reports of the distribution of time or effort for professional staff members. ➢ Time and attendance and payroll distribution records for non-professional employees. ◆ Non-profit organizations ➢ Monthly after-the-fact reports, including a signed certification, by the employee, or by a responsible supervisory official having first-hand knowledge of the work performed, that the distribution of activity represents a reasonable estimate of the actual work performed by the employee during the period covered by the report. Each report must account for the total activity required to fulfill the employee's obligations to the organization as well as the total activity for which he or she is compensated. ➢ For non-professional employees, additional supporting reports, indicating the total number of hours worked each day, must be maintained in conformance with DoL regulations implementing the Fair Labor Standards Act (29 CFR Part 516). ➢ The distribution of salaries and wages must be supported by personnel activity reports as described above, except when a substitute system has been approved, in writing, by the Federal cognizant agency designated under OMB Circular A-122. ◆ State, local, and Indian tribal governments ➢ Time and attendance or equivalent records for all employees. ➢ Time distribution records for employees whose compensation is chargeable to more than one grant or other cost objective. ◆ Educational institutions ➢ A plan confirmation system for professorial and other professional staff members that is based on budgeted, planned, or assigned work activity and that is updated to reflect any significant changes in work distribution. This system must be incorporated into the organization's official records and must identify activity applicable to each sponsored agreement and to each category needed to identify F&A costs and the functions to which they are allocable. At least annually, the employee, PI, or responsible officials will verify, by suitable means, that the work was performed and that the salaries and wages charged to sponsored agreements, whether as direct charges or in other categories of cost, are reasonable in relation to the work performed; or

	➢ A system, supported by after-the-fact activity reports, that reflects the distribution of covered employees' activity allocable to each NIH grant and includes identification and recording of significant changes in work activity when initial charges were based on estimates. The system also must specify each category of activity needed to identify F&A costs and the functions to which they are allocable. For professorial and other professional staff members, the activity reports will be prepared each academic term, but at least every 6 months. For other employees, unless NIH agrees to alternate arrangements, the reports will be prepared at least monthly and will coincide with one or more pay periods; or ➢ A multiple confirmation records system, for professorial and other professional staff members, that is supported by records certifying costs separately for direct costs and F&A costs, with reports prepared each academic term, but at least every 6 months, that confirm the activities as allocable to direct or F&A costs; or ➢ By mutual agreement, any other method meeting the criteria specified in paragraph J.8.b.(2) of OMB Circular A-21. ◆ For-profit organizations ➢ NIH requires for-profit organizations to conform with industry standards to support salary and wage charges to NIH grants. Therefore, unless an alternate system is approved by the GMO, the grantee must maintain a time-and-effort reporting system for both professional and other-than-professional staff reflecting daily after-the-fact reporting of hours expended on individual projects or indirect activities. The system must record both hours worked and hours absent. This information must be certified by an AOO no less frequently than every pay period.
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 formal policies of the organization consistently applied regardless of the source of funds.
Bonus Funds/Incentive Payments	Allowable as part of a total compensation package, provided such payments are reasonable and are made according to a formal policy of the grantee that is consistently applied regardless of the source of funds.
Payments for Dual Appointments	For investigators with university and clinical practice plan appointments, compensation from both sources may be considered the base salary if the following criteria are met: ◆ Clinical practice compensation must be guaranteed by the university ◆ Clinical practice effort must be shown on the university appointment form and must be paid through the university ◆ Clinical practice effort must be included and accounted for on the university's effort report.
Support from Multiple Grants	See "Cost Considerations—Allocation of Costs and Closely Related Work."

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: ◆ The individual is performing activities necessary to the grant ◆ 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 ◆ 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. Charges for tuition remission and other forms of compensation paid to students as, or 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. The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is tied to 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). 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 and computer services, are allowable and 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 Subpart B of this part. Stipends are not allowable under research grants even when they appear to benefit the research project.
Subject Costs	See "Research Patient Care" in this subsection.

Supplies	Allowable.
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 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. 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 office.
	A trailer or modular unit is considered equipment when the unit and its installation are designed or planned to be used at any given location for a limited time only. Units classified as equipment may be charged to NIH grant-supported projects only if the terms and conditions of the award do not prohibit the purchase of equipment and NIH prior approval is obtained, as appropriate. A trailer or modular unit properly classified as real property or as equipment at the time of acquisition retains that classification for the life of the item, thereby determining the appropriate accountability requirements under 45 CFR 74.32 or 74.34 or 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 Subpart B of this part for detailed information.)
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.
Employees	Consistent with the organization's established travel policy, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile. Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the United States and its possessions and territories and also travel between the United States and Canada and within Canada. Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country. In all cases, travel costs are limited to those allowed by formal 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 formal travel policy, those regulations will be used to determine the amount that may be charged for travel costs.
	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). Grantees must comply with the requirement that U.S. flag air carriers be used by domestic grantees 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 must not be influenced by factors of cost, convenience, or personal travel preference. The cost of travel under a ticket issued by a U.S. flag air carrier that leases space on a foreign air carrier under a code-sharing agreement is allowable if the purchase is in accordance with GSA regulations on U.S. flag air carriers and code shares (http://www.gsa.gov/gsa/cm_attachments/GSA_DOCUMENT/110304_FTR_R2QA53_0Z5RDZ-i34K-pR.pdf). (A code-sharing agreement is an arrangement between a U.S. flag carrier and a foreign air carrier in which the U.S. flag carrier provides passenger service on the foreign air carrier's regularly scheduled commercial flights.) 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.
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 "Research Patient Care.")

ADMINISTRATIVE REQUIREMENTS

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 B of this part. 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 from, the awarding office GMO in advance of the change or obligation of funds as specified below under "Requests for Prior Approval."

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

Expanded Authorities

NIH has waived cost-related and other prior-approval requirements for many activities and expenditures, and provided authority for these activities and expenditures to the grantee. These operating authorities are termed "expanded authorities." Exhibit 3 presents a summary of expanded authorities. Certain award instruments, mechanisms, and types of recipients are excluded from the expanded 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; and awards to individuals.

Certain grants or grantees also may be excluded from expanded authorities, including those that require closer project monitoring or technical assistance, and certain large multi-project grants. If excluded from some or all expanded authorities, the NGA will indicate this change from the standard terms and conditions. In addition, one or more of these authorities may be overridden by a special term or condition of the award. Therefore, grantees must review the NGA to determine whether and to what extent they are permitted to use expanded authorities.

When using expanded authorities, grantees must ensure that they exercise proper stewardship over Federal funds and 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 expanded authorities have specific deadlines for submission of reports or for timely notification to the NIH awarding office. 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 expanded authorities.

Exhibit 3. Summary of Expanded Authorities	
May exercise as expanded authority	**Except**
Carryover of unobligated balances from one budget period to the next	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, and awards to individuals, or if the NGA indicates otherwise.
Cost-related prior approvals, including research patient care costs and equipment	If the scope would change.
Extension of final budget period of a project period without additional NIH funds	If the grantee already has given itself one extension of up to 12 months.
Transfer of performance of substantive programmatic work to a third party (by consortium agreement)	If the transfer would be to a foreign component or it would result in a change in scope.

Carryover of Unobligated Balances from One Budget Period to Another Within an Approved Project Period. Awards routinely excluded from the automatic carryover of unobligated balances include 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 mechanism), and awards to individuals. For these mechanisms, carryover of unobligated balances always requires NIH awarding office prior approval unless that requirement is waived by a term or condition of the NGA. Other awards may be excluded from use of this authority through a special term or condition in the NGA.

For awards using 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 its grant progress report, whether its estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. If so, the grantee must provide an explanation and indicate plans for expenditure of those funds.

For those awards subject to expanded authorities but excluded from SNAP, the FSR must specify the amount to be carried over. The notification must be provided under item 12, "Remarks," on the FSR. When a grantee reports a balance of unobligated funds in excess of 25 percent of the total amount awarded, 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.

Whether or not under SNAP, 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 NGA.

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. This also includes research patient care as described in the NIHGPS.

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 NGA if

- no additional funds are required to be obligated by the NIH awarding office,
- the project's originally approved scope will not change, and
- any one of the following applies:
  - Additional time beyond the established expiration date is required to ensure adequate completion of the originally approved project.
  - Continuity of NIH grant support is required while a competing continuation application is under review.
  - The extension is necessary to permit an orderly phase-out of a project that will not receive continued support.

The fact that funds remain at the expiration of the grant is not, in itself, sufficient justification for an extension without additional funds.

The grantee must notify the NIH awarding office, in writing, of the extension 10 days before the expiration date of the project period. Upon notification, the NIH awarding office will revise the project period ending date and provide an acknowledgment to the grantee. In extending the final budget period of the project period through this process, the grantee agrees to update all required certifications and assurances, including those pertaining to human subjects and animal welfare, in accordance with applicable regulations and policies. Grantees may not extend project periods previously extended by the NIH awarding office. Any additional project period extension beyond the one-time extension of up to 12 months requires NIH prior approval. (See "Prior-Approval Requirements" in this section for extensions requiring additional funds.) Grantees are reminded that all terms and conditions of the award apply during the extended period.

Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement. Prior approval by the NIH awarding office is not required to transfer the performance of substantive programmatic work unless the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

Prior-Approval Requirements

This subsection describes the activities and/or expenditures that require NIH prior approval. NIH prior-approval requirements are summarized in Exhibit 4, 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 and whether or not the grant also is subject to expanded authorities. The circumstances under which prior approval is required also are summarized in the exhibit.

Grantees also should consult Subpart B of this part 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 4. Summary of Actions Requiring NIH Prior Approval

NIH prior approval is required for	Under the following circumstances
A&R	Rebudgeting into A&R costs that would exceed 25 percent of the total approved budget for a budget period. If rebudgeting would not meet this threshold but would result in a change in scope. Any single A&R project exceeding $300,000.
Capital expenditures (construction, land, or building acquisition)	All instances when purchase proposed; any proposal to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds.
Change in scope	All instances.
Changes in status of key personnel	Withdrawal from the project; absence for any continuous period of 3 months or more; reduction of time devoted to project by 25 percent or more from level in approved application.
Change of grantee organization	All instances.
Carryover of unobligated balances	If the NGA indicates that the grantee does not have the authority to automatically carry over balances.
Deviation from award terms and conditions	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	All instances.
Need for additional NIH funding	All instances, including extension of a final budget period of a project period with additional funds.
Pre-award costs	More than 90 days before effective date of the initial budget period of a new or competing continuation award, at grantee's own risk.
Retention of research grant funds when K award made	All instances.

Exhibit 4. Summary of Actions Requiring NIH Prior Approval	
NIH prior approval is required for	**Under the following circumstances**
Second no-cost extension or extension greater than 12 months	All instances.
Transfer of funds between construction and nonconstruction work	All instances.
Transferring amounts from trainee costs	All instances.

Alterations and Renovations. NIH prior approval is required if a grantee rebudgets 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 $300,000, NIH always will consider the rebudgeting to be a change in scope. (See "Construction Grants—Administrative Requirements—Prior-Approval Requirements—Alteration and Renovation Projects under Nonconstruction Grants" in Subpart B of this part for documentation requirements for A&R projects exceeding $300,000).

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 office or its successor organization.

Change in Scope. In general, the 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 office for a change in the direction, type of research or training, or other areas that constitute a significant change from the aims, objectives, or purposes of the approved project (hereafter "change in scope"). The grantee must make the initial determination of the significance of a change and should consult with the GMO as necessary.

Actions likely to be considered a change in scope and, therefore, requiring NIH awarding office prior approval 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.
- Any change from the approved use of animals or 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.

- 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, this type of action always requires NIH prior approval.

- Change in key personnel (see "Change in Status, Including Absence, of Principal Investigator and Other Key Personnel" for requirements for NIH approval of alternate arrangements for or replacement of 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 more than 25 percent 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.

- 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.

Change in Status, Including Absence, of Principal Investigator and Other Key Personnel. The grantee is required to notify the GMO in writing if the PI or key personnel specifically named in the NGA 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 award (for example, a proposed change from 40 percent effort to 30 percent or less effort). NIH must approve any alternate arrangement proposed by the grantee, including any replacement of the PI or key personnel named in the NGA.

The request for approval of a substitute PI/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 office, 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 the PI and those key personnel NIH names in the NGA regardless of whether the applicant organization designates others as key personnel for its own purposes.

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 grant to be transferred has been terminated in accordance with 45 CFR 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").

- 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 PI on a research project transferring from one organization to another organization. The project under the same PI may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable F&A costs) for the remaining period.

A 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. However, an individual fellowship may be transferred to a new sponsoring organization. The transfer process will be the same as for a change of grantee organization. A change in an individual fellow's department or sponsor within the same organization is not considered a change of grantee organization. A successor-in-interest or a name change is not considered a change of grantee (see "Change in Grantee Organizational Status" in this section).

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 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 a delay in processing.

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 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 office may require peer review or may disapprove the request and, if appropriate, terminate the award.

A request for a change of grantee organization must be submitted to the GMO and must include an Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant (PHS 3734) (relinquishing statement) and a Final Invention Statement and Certification from the original grantee as well as an application (PHS 398 or 416-1) from the proposed grantee or sponsoring organization. (A final FSR is due to NIH from the relinquishing organization no later than 90 days after the end of NIH support of the project.) If the original award was the result of a modular application, modular procedures apply to the request for change of grantee. For awards using the PHS 398, 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 PI and existing key personnel and biographical sketches for any proposed new key personnel
- Statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, providing updated information
- Updated "other support" page(s), if necessary
- Resources page
- Checklist page
- Certification of IRB/IACUC approval, if applicable
- Detailed list of any equipment purchased with grant funds being 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 NGA 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 an NGA reflecting the balance reported on the relinquishing statement or, if the change of grantee organization occurs on the anniversary date of the project, the NGA to the new grantee will reflect the previously committed direct cost level plus applicable F&A costs). This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward.

Change in Grantee Organizational Status. Grantees must give NIH advance notice of the following types of change in organizational status (that are not considered to be a change of grantee organization as described in this subsection):

- *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.* 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). An 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 still is 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 awarding office 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 office ordinarily will be the IC with which the organization has the most NIH grants. If there is no advance consultation, 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 an SII, a letter signed by the AOOs of the current grantee (transferor) and the successor-in-interest (transferee) must be sent to the lead NIH awarding office, following consultation with the GMO of that awarding office. The letter must do the following:

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

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

- Request that the NIH awarding office(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 Entity Identification Number.
- Include verification of the transferee's compliance with applicable requirements (e.g., research misconduct).
- 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 of PI.
  - 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 both the PI and the AOO 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. Upon review and acceptance of this information, NIH will revise the NGA(s) to show the transferee as the grantee of record.

For name changes, the grantee's written notification to the lead NIH awarding office must include the effective date of the change. Revised face pages are not required for name changes because name changes are processed with the next award action (e.g., non-competing continuation award) and the organization will submit a face page with the new information as part of that action.

Deviation from Award Terms and Conditions, including Restrictions on the NGA. NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NGA, including those in the NIHGPS. This includes undertaking any activities disapproved or restricted as a condition of the award.

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.

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 competing continuation 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.

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 to provide continuity of project activities while a competing continuation application is being reviewed or to permit orderly phaseout 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.

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

Retention of Research Grant Funds When a K Award is Made. 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.

Transfer of Amounts from Trainee Costs. The transfer 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 Subpart B of this part).

Transfer of Funds Between Construction and Nonconstruction Work. Under awards that provide for both construction and nonconstruction work, NIH prior approval is required to transfer funds between the two types of work.

Requests for Prior Approval

All requests for NIH awarding office prior approval must be made in writing (which includes submission by e-mail) to the GMO no later than 30 days before the proposed change. The request must be signed by both the PI and the AOO. Failure to obtain required prior approval, from the appropriate NIH awarding office 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 AOO to the GMO that signed the NGA. (E-mail addresses for NIH staff can be obtained from the NIH Directory and E-Mail Forwarding Services at http://directory.nih.gov.) E-mail requests must include the name of the grantee, the name of the initiating PI, the PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOO. If the entire message of the request cannot be included in the body of the e-mail, the request should be submitted to NIH in hard copy.

The GMO will review the request and provide a response to the AOO indicating the final disposition of the request. The GMO will provide copies of the response to the PI and to the cognizant NIH PO. Only responses provided by the GMO are to be 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 grantee. However, the 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 grantee must obtain that approval from NIH before giving its approval to the consortium participant.

Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. 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 "Public Policy Requirements and Objectives—Availability of Information—Access to Research Data" 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.

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,[12] or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. 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 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 office in advance to allow for coordination.

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[12] 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.

One copy of each publication resulting from work performed under an NIH grant-supported project must accompany the annual or final progress report submitted to the NIH awarding office (see "Administrative Requirements—Monitoring—Reporting—Non-Competing Grant Progress Reports" and "Administrative Requirements—Closeout—Final Reports—Final Progress Report").

Sharing of Research Data

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. Effective with the October 1, 2003 receipt date, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single budget period are expected to include a plan for data sharing or state why data sharing is not possible.

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 "Privacy Rule" (See "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Confidentiality—Standards for Privacy of Individually Identifiable Health Information"). 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.

Sharing of Unique Research Resources

Investigators conducting biomedical research frequently develop unique research resources. Categories of these resources include synthetic compounds, organisms, cell lines, viruses, cell products, and cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized or genetically defined cells, including normal and diseased human cells; monoclonal antibodies; hybridoma cell lines; microbial cells and products; viruses and viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; certain types of animals, such as transgenic mice; and intellectual property, such as computer programs.

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 developed with NIH funds and the associated research findings have been published 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.

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), which is available on the NIH website (http://www.ott.nih.gov/policy/rt_guide_final.html). 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 office, 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 biological materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories. 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.

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 comply with these requirements should promptly contact the GMO to discuss the circumstances, obtain information that might enable compliance, and reach an understanding in advance of an award.

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.

NIH grantees may retain intellectual property rights to subject inventions provided they do the following:

- 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 5 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.

Exhibit 5. Extramural Invention Reporting Compliance Responsibilities

Action required	When action must be taken	Discussion	37 CFR 401 reference
Employee Agreement to Disclose All Inventions			
The PI (employee) 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.	Grantee organizations and consortium participants must have policies in place regarding ownership of intellectual property.	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.	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) 401.14(c)(1)

Exhibit 5. Extramural Invention Reporting Compliance Responsibilities			
Action required	**When action must be taken**	**Discussion**	**37 CFR 401 reference**
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) 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) 401.14(c)(2) 401.14(f)(1)
Confirmatory License			
For each invention, the grantee must provide a use 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.	401.14(c)(3) 401.2(n)
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. 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.	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)

Exhibit 5. Extramural Invention Reporting Compliance Responsibilities			
Action required	**When action must be taken**	**Discussion**	**37 CFR 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 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 (https://s-edison.info.nih.gov/iEdison/).	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 grant progress reports.	The information is requested as a checklist item on the PHS 398 application and on the non-competing grant progress report.	PHS 398 and PHS 2590
Final Invention Statement and Certification			
The grantee must submit to the NIH awarding office 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)

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 74. and 37 CFR 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 following address:

Extramural Inventions and Technology Resources Branch
Division of Grants Policy
Office of Policy for Extramural Research Administration
Office of Extramural Research
NIH
6705 Rockledge Drive, MSC 7980
Bethesda, MD 20892-7980
301-435-1986 (voice)
301-480-0272 (fax)

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 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.

Financial Management System Standards

Grantees are required to meet the standards and requirements for financial management systems set forth or referenced in 45 CFR 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.

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; 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.) 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 PI has a history of frequent, large annual unobligated balances on previous grants; or if the 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.

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.

Program income earned during the period of grant support (other than income earned as a result of copyrights, patents, or inventions or as a result of the sale of real property, equipment, or supplies) shall be retained by the grantee and, as specified by NIH in the NGA, may be used in one or a combination of the ways indicated in Exhibit 6.

Exhibit 6. 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.

Sale of Real Property, Equipment, and Supplies

The requirements that apply to the sale of real property are addressed in "Construction Grants." 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 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 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.

Reporting of Program Income

The amount of program income earned and the amount expended must be reported on the FSR (SF 269—Long Form). 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 subject to the additive alternative must be reported on lines 10r and 10s, as appropriate, of the FSR; program income subject to the deductive alternative must be reported on lines 10c and 10q of the FSR; and program income subject to the matching alternative must be reported on lines 10g and 10q of the FSR. (See "Administrative Requirements—Monitoring—Reporting—Financial Reporting.") For awards under SNAP, the amount of program income earned must be reported in the non-competing grant progress report.

Income resulting from royalties or licensing fees is exempt from reporting as program income.

Income earned from the sale of equipment must be reported on the FSR 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 line 10c of the FSR.

When the terms of the NGA, including the NIHGPS, do not specify any accountability requirement for income earned, no reporting of income is required. Reporting requirements for accountable income accrued after grant support ends will be specified in the NGA.

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 NGA 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 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 ("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").

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 74.31 through 74.37 or 92.31 through 92.34,[13] as applicable, and the following.

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 74.2, the 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"), 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 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 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.

Real Property

See "Construction Grants—Administrative Requirements—Real Property Management Standards" 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.

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 74.31, 74.34, 74.35, and 74.37, or 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

[13] 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 92.32.

charged, donated equipment, or equipment acquired primarily for sale or rental rather than for use.

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 office under the conditions specified in 45 CFR 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 74.34(h)(2), whichever is later.

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 74.34 and 74.35, or 45 CFR 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 74.21 or 92.20. Pursuant to 45 CFR 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 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 office under the conditions specified in 45 CFR 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 office for its share as a credit to the grant.

Recipients of NIH grants must not use equipment acquired with grant funds to provide services for a fee to compete unfairly with private companies that provide equivalent services, unless the terms and conditions of the award provide otherwise.

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 45.5 (the FAR).

Procurement System Standards and Requirements

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 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."

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 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 office has been made aware of this situation either at the time of application or through post-award notification.
- The project has been recommended for a project period extending beyond the current year of support.
- The 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 74.48 and 92.36(i)(2) specify termination provisions for contracts in excess of $100,000.

Approval Requirements

The procurement standards in 45 CFR 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.

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 are required to take the following steps to implement this policy:

- Place qualified small, minority, and women-owned business enterprises on solicitation lists.
- Ensure that small, minority, and women-owned business enterprises are solicited whenever they are potential sources.
- Consider contracting with consortia of small businesses, minority-owned businesses, or women's business enterprises when an intended contract is too large for any one such firm to handle on its own or, if economically feasible, divide larger requirements into smaller transactions for which such organizations might compete.
- Make information on contracting opportunities available and establish delivery schedules that encourage participation by small, minority, and women-owned business enterprises.
- Use the services and assistance of the SBA and DoC's Minority Business Development Agency, as appropriate.
- If subcontracts are to be let, require the prime contractor to take the affirmative steps listed above.

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 offices 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").

Reporting

NIH requires that grantees periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, 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 and 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 receipt point for most required reports, including non-competing and final grant progress reports, final invention statements and certifications, and lobbying disclosure statements. Non-competing grant progress reports must be submitted in an original and two copies. Submission of these reports to individuals other than the GMO may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FSRs are to be submitted to OFM (see "Financial Reports" in this subsection) 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 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 expanded authorities, or conversion to a reimbursement payment method (also see "Administrative Requirements—Enforcement Actions"). The schedule for submission of the non-competing grant progress report is discussed in the next subsection.

Non-Competing Grant Progress Reports

Progress reports usually are required annually as part of the non-competing continuation award process. However, NIH may require these reports more frequently. The "Grant 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 non-competing grant progress reports are available at http://grants.nih.gov/grants/funding/2590/2590.htm.

Non-competing grant progress reports must be submitted directly to the awarding office. Grantees should routinely query and review the list of pending grant progress reports and due dates available at the NIH website (http://era.nih.gov/userreports/pr_due.cfm). 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 office will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, and nonconstruction activities.

Streamlined Non-Competing Award Process

The NGA will specify whether an award is subject to SNAP. Award mechanisms routinely included in SNAP are "R" awards, with the exception of R35 and K awards. Award mechanisms excluded From SNAP are those that do not have the expanded 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 mechanism), P01, R35, and awards to individuals. In addition, individual awards under any mechanism may be excluded from SNAP if

- 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.

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. As a result, for awards under SNAP, grantees are required to submit only limited portions of the Grant Progress Report. 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.

As part of the progress report, grantees must answer the following questions:

- Has there been a change in the "other support" of key personnel since the last reporting period? If so, the changes, including termination of a previously active grant or activation of a previously pending grant, must be explained. If not, the grantee must so state.

- In the next budget period, will there be a significant change in the level of effort for key personnel from what was approved for this project? A "significant change" is a 25 percent or greater reduction in time devoted to the project. If so, the grantee must explain. If not, the grantee must so state.

- Does the grantee anticipate that it will have an estimated unobligated balance (including prior-year carryover) that will be greater than 25 percent of the current year's total budget? If so, the grantee will be required to explain why there is a significant balance and how it will be spent if carried forward into the next budget period. If not, the grantee should so state.

The awarding office will rely on the grantee's assessment of whether significant changes have occurred or will occur in these areas; however, the GMO may require additional information to evaluate the project for continued funding. Failure to provide this information will result in a delayed award.

For awards under SNAP (other than awards to foreign organizations or Federal institutions), an FSR is required only at the end of a competitive segment rather than annually. The FSR 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 FSR (see "Administrative Requirements—Closeout"). For awards under SNAP, grantees (other than foreign grantees and Federal institutions) also are required to submit a quarterly FCTR (SF 272) to PMS. Foreign organizations and Federal institutions must submit an annual FSR even if an award is under SNAP. (Also see "Administrative Requirements—Monitoring—Reporting—Financial Reports.")

Financial Reports

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the grantee organization. Financial or expenditure reporting is accomplished using the FSR (SF 269 or SF 269 A); the grantee must use the long form (SF 269) to report program income earned and used.

Except for awards under SNAP and awards that require more frequent reporting, the FSR is required on an annual basis. An annual FSR 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 close of the budget period. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NGA will specify both the frequency and due date.

For domestic awards under SNAP, in lieu of the annual FSR, NIH will use the quarterly FCTR, submitted to PMS to monitor the financial aspects of grants. 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 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 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 (see "Administrative Requirements—Closeout").

FSRs may be transmitted electronically to OFM through NIH's eRA Commons website at https://commons.era.nih.gov/commons. Before submitting FSRs to NIH, grantees must ensure that the information submitted is accurate, complete, and consistent with the grantee's accounting system. The AOO's signature on the FSR certifies that the information in the FSR 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.

Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. (See "Administrative Requirements—Changes in Project and Budget" for NIH approval authorities for unobligated balances.) Using the principle of "first in-first out," unobligated funds carried over are expected to be used before newly awarded funds.

Upon receipt of the annual FSR 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 NGA 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.

In some cases the grantee may have to revise or amend a previously submitted FSR. When the revision results in a balance due to NIH, the grantee must submit a revised FSR 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 to the GMO 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 office will advise the grantee of actions it will take to reflect the adjustment. NIH will not accept any revised report received after that date and will return it to the grantee.

Invention Reporting

A complete list of the reporting requirements under the Bayh-Dole Act can be found at 37 CFR 401.14. The requirements also are specified in "Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources."

In addition to complying with Bayh-Dole-related regulations, each NIH competing grant application and non-competing 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 may result in the loss of patent rights or a withholding of grant funds.

Bayh-Dole regulations allow grantees to report inventions electronically (37 CFR 401.16). NIH strongly supports electronic reporting through an Internet-based system, Interagency Edison (https://s-edison.info.nih.gov/iEdison/). 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 NIH at

Extramural Inventions and Technology Resources Branch
Office of Policy for Extramural Research Administration
Office of Extramural Research
NIH
6705 Rockledge Drive, MSC 7980
Bethesda, MD 20892-7980
edison@od.nih.gov
1-866-504-9552 (toll-free)
301-480-0272 (fax)

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 FSR 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 FSR 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 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). 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 74.48 and 92.36 for record retention and access requirements for contracts under grants.

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 74.26 and 92.26, or the audit requirements stated in 45 CFR 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 sections of this NIHGPS that provide specific requirements for those types of grantees.

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 made 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 following address:

  Federal Audit Clearinghouse
  Bureau of the Census
  1201 E. 10th Street
  Jeffersonville, IN 47132
  (http://harvester.census.gov/sac/)

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—Selected Items of Cost" for the allowability of audit costs.

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. If NIH imposes sanctions on a grantee as a result of research misconduct or will more closely monitor an award(s) through the use of special conditions, NIH will share this information with other HHS components.

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 52.9 and 45 CFR 74.14 or 92.12.

The awarding office also may withdraw approval of the PI or other key personnel if there is a reasonable basis to conclude that the PI and other key personnel are no longer qualified or

competent to perform. In that case, the awarding office may request that the grantee designate a new PI or other key personnel.

The decision to modify the terms of an award—by imposing special conditions, by withdrawing approval of the PI or other key personnel, or otherwise—is discretionary on the part of the NIH awarding office.

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 74.61 and 74.62, and in 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—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.
- 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.

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 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 is a distinct action from "suspension" as a post-award remedy described under "Suspension, Termination, and Withholding of Support" in this subsection. The subject of debarment and suspension as an eligibility criterion is addressed in "Completing the Pre-Award Process—Eligibility" and "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Debarment and Suspension."

Recovery of Funds

NIH may administratively recover funds paid to a grantee in excess of the amount to which the grantee is finally determined to be entitled under the terms and conditions of the award, including misspent funds or unallowable costs incurred. If the grantee does not pay back the funds in accordance with the demand by the awarding office, which specifies the period of time for repayment, the awarding office may collect the debt by

- making an administrative offset against payments that would be due under other grant awards,
- withholding advance payments that would otherwise be due, or
- taking any other action permitted by statute.

Debt Collection

The Federal Debt Collection Act (Act) (31 U.S.C. 3711) and the Federal Claims Collection Standards (4 CFR Parts 101-105) require NIH 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 (also see HHS claims collection regulations at 45 CFR Part 30). Debts may result from cost disallowances, recovery of funds, unobligated balances, or other circumstances.

Unless otherwise specified in law, regulation, or the terms and conditions of the award, debts are considered delinquent 30 days after notification to the grantee of the indebtedness. The interest on delinquent debts will be computed from the original notification date to the grantee of the indebtedness. The interest rate applied will be the current value of funds rate or the private consumer rate of interest fixed by Treasury, whichever is higher. A higher rate may be charged if necessary to protect the interests of the Federal government.

Penalties and administrative collection costs also will be charged in accordance with the Act and the implementing HHS regulations, as follows:

- A penalty charge of 6 percent a year will be assessed on debts that are more than 90 days overdue. Penalty charges will accrue from the date the debt became overdue until the indebtedness is paid.
- Delinquent debtors will be assessed charges to cover the Federal government's administrative costs of collecting overdue debts. From time to time, HHS will publish a notice in the *Federal Register* setting forth the amounts to be assessed for administrative collection costs.

If a grantee appeals an adverse monetary determination under 42 CFR Part 50, Subpart D, or 45 CFR Part 16, collection will be suspended pending a final decision on the appeal. If the determination is sustained (either fully or partially), interest will be charged beginning with the date of the original notification to the grantee of the indebtedness.

Closeout

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 74.71 through 74.73 and in 45 CFR 92.50. Closeout includes ensuring timely 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.

Final Reports

Unless the GMO grants an extension, grantees must submit a final FSR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant support. Failure to submit timely and accurate final reports may affect future funding to the organization or awards with the same PI.

Final Financial Status Report

A final FSR 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.

The final FSR must cover the period of time since the previous FSR submission or, for awards under SNAP, the entire competitive segment or as much of the competitive segment as has been

funded before termination. Final FSRs must have no unliquidated obligations and must indicate the exact balance of unobligated funds. 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 office. 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 FSR 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.
- 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.

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. The final progress report should include a summary of progress toward the achievement of the originally stated aims, a list of significant results (positive or negative), and a list of publications. The final progress report also should address the following:

- 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—Requirements for Inclusiveness in Research Design—Inclusion of Children as Subjects in Clinical Research" and the PHS 398)
- 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.

An original and one copy of this report should be submitted to the GMO.

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. 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 the PI and an AOO. 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 office. If there were no inventions, the form should indicate "None." Copies of the HHS 568 form are available on the iEdison website at https://s-edison.info.nih.gov/iEdison/.

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 grantee's request to NIH for review must be postmarked no later than 30 days after receipt of the written notification of the adverse determination; however, an extension may be granted if the grantee can show good cause why an extension is warranted (42 CFR 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 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).[14]

[14] 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.

Important Note:

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

http://grants1.nih.gov/grants/policy/nihgps_2003/nihgps_2003_2_of_2.pdf

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

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

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

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