NIH GRANTS POLICY STATEMENT

NIH Grants Policy Statement

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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, up-to-date policy guidance that will serve as the terms and conditions of NIH awards. This document is also 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 in hard copy format from the office specified in "Maintenance" below and on-line from the NIH Home Page at **http://www.nih.gov** (access the "Grants" link under "Funding Opportunities," then click on the "Grants Policy" page).

To accomplish these objectives, the document is set up in four parts: the first part includes general information about NIH and its grant application and review processes; the second part provides the standard terms and conditions of NIH awards; the third part consists of terms and conditions that apply to particular types of grants/grantees/activities that differ from or supplement those in Part II; and the fourth part includes a listing of pertinent offices and officials with their addresses and telephone numbers. This format allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions.

Part I

Part I provides a glossary of commonly used terms; 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 application and review processes; and explains the various resources available to those interested in the NIH grants process.

Part II

Part II serves as the overall set of terms and conditions that will be incorporated by reference in all NIH grant awards. This Part includes generally applicable requirements, which may be either in the form of full text or reference to or highlighting of statutory, regulatory, or Office of Management and Budget (OMB) requirements.

Part III

Part III specifies, in separate sections, requirements that pertain to construction grants; training grants and fellowships; conference grants; consortium agreements; grants to foreign and international organizations (and domestic grants with substantial foreign components); grants to Federal institutions and payments to (or on

behalf of) Federal employees; grants to for-profit organizations; and research patient care activities.

Part IV

Part IV contains general information such as names, telephone numbers, and Web site addresses to aid the reader.

Certain conventions are followed throughout this document. The term "grant" is used to mean both "grants and cooperative agreements." The term "grantee" is used to refer to recipients of grants and awardees of cooperative agreements, unless the context requires use of a generic or alternate term, such as "recipient" or "awardee," for clarity. "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 Institutes or Centers, with an action by a grantee or other organization. References to "Part II," "Part III," or "Part IV" without further elaboration mean the corresponding part of this policy statement

BACKGROUND AND SUPERSESSION

Applicants for NIH grants and grantees have historically relied on a variety of sources for information about NIH's grants process and requirements. While many of these sources were developed and maintained by NIH, the primary source of information for grantees was *the Public Health Service (PHS) Grants Policy Statement*. That document was issued by the Office of the Assistant Secretary for Health, an organizational level that has been eliminated as part of HHS' streamlining efforts. The NIH decision to publish its own policy statement is based on the need to provide its grantees with updated information as well as its desire to enhance its method of communicating about its grants policies and process. Although much of the content of the NIHGPS may be applicable to grants awarded by other PHS or HHS components, NIH has developed this document for its own purposes.

The NIHGPS is effective for all NIH grants and cooperative agreements (hereafter, "grants") for budget periods beginning on or after October 1, 1998, and will supersede, in its entirety, the *PHS Grants Policy Statement*, dated April 1, 1994, and addendum, dated January 24, 1995. While the NIHGPS has been reformatted as described above, most of the actual changes to the content of the prior *PHS Grants Policy Statement* are technical amendments to reflect current requirements rather than substantive changes in policy. An explanation of the major changes from the *PHS Grants Policy Statement* is included in the *NIH Guide for Grants and Contracts* (NIH Guide) notice announcing the issuance of the NIHGPS. The NIH Guide is published on the NIH Home Page at **http://www.nih.gov** (access the "grants" link under "Funding Opportunities," then click on the "NIH Guide" page).

MAINTENANCE

The Office of Policy for Extramural Research Administration (OPERA) is responsible for developing and maintaining this document, which will be reissued periodically in hard-copy format. Interim changes will be published in the NIH Guide. Each change will be described, including its applicability and effective date; the affected section(s) of the NIHGPS specified; and the necessary language to implement it as a term or condition of award provided. Concurrently, conforming changes will be made in the electronic version of the NIHGPS (see access information above) with a date indicator showing the change's effective date. Grantees will be responsible for reviewing the NIH Guide for changes and for implementing them, as appropriate.

The OPERA staff welcomes comments and suggestions for future versions of the NIHGPS (see Part IV for address and telephone and fax numbers).

Part I: NIH Grants—General Information

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GLOSSARY

This glossary defines terms commonly used throughout this policy statement. These 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.

This glossary also includes a list of commonly used acronyms and other abbreviations.

Definitions

Application: A request for financial support of a project/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 as well as 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 initial Notice of Grant Award 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 Institutional 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.

Award: The provision of funds by NIH, based on an approved application and budget, to an organizational entity or an individual to carry out an activity or project.

Awarding Office: The NIH Institute or Center responsible for the award, administration, and monitoring of grant-supported activities.

Budget Period: The interval of time (usually 12 months) into which a project period is divided for budgetary and funding purposes.

Competitive Segment: The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from the award of a competing continuation grant that establishes a new competitive segment for the project.

Consortium Agreement: A collaborative arrangement in support of a research project in which some portion of the programmatic activity is carried out through a formalized agreement between the grantee and one or more other organizations that are separate legal entities administratively independent of the grantee.

Contract Under a Grant: A written agreement between a grantee and a third party to acquire routine goods or services.

Cooperative Agreement: A financial assistance mechanism used when substantial Federal programmatic involvement with the recipient during performance is anticipated by the NIH Institute or Center.

Cost Sharing: See "Matching or Cost Sharing."

Direct Costs: Costs that can be specifically identified with a particular project(s) or activity.

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 the lesser of the capitali-

zation threshold established by the organization or $5,000.

Expanded Authorities: The operating authorities provided to grantees under certain research grant mechanisms that waive the requirement for NIH prior approval for specified actions.

Expiration Date: The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Facilities and Administrative Costs: Costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. These costs were previously known as "indirect costs," and, in most instances, will be referred to in this document as "F&A costs."

Federal Demonstration Partnership: A cooperative initiative among some Federal agencies, including NIH; select organizations that receive Federal funding for research; and certain professional associations. Its efforts include a variety of 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.

Financial Assistance: Transfer by NIH of money or property to an eligible entity to support or stimulate a public purpose authorized by statute.

Foreign Organization: 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 principal investigator.

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 are also referred to as "commercial organizations."

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 awarding office anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grant-Supported Project/Activities: Those programmatic activities specified or described in a grant application or in a subsequent submission(s) that are approved by an NIH Institute or Center 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 activities. The grantee is the entire legal entity even if a particular component is designated in the award document. 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 (GMO): 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 to make changes to approved projects on behalf of NIH. Each NIH Institute and Center that awards grants has one or more GMOs with responsibility for particular programs or awards.

Indirect Costs: See "Facilities and Administrative Costs."

Institute/Center (IC): The NIH organizational component responsible for a particular grant program(s) or set of activities. The designated GMO and Program Official for that program or set of activities are employees of the IC. **Use of the terms "NIH IC" or "awarding office" throughout this document to designate a point of contact for advice and interpretation of grant requirements and establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award refers specifically to the IC Grants Management Officer.**

International Organization: An organization that identifies itself as international or intergovernmental, 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: Individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project. The principal investigator is included in this category.

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 Institute or Center. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

Misconduct in Science: Fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research. The term does not include honest error or honest differences in interpretations or judgments of data.

Monitoring: A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

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, that receives and/or applies for an NIH grant or cooperative agreement.

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 for the proper conduct of the project or activity.

Prior Approval: Written approval from the Institute or Center Grants Management Officer required for specified postaward changes in the approved project or budget. Such approval must be obtained prior to undertaking the proposed activity or spending NIH funds.

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 purposes of this policy statement, "program" refers to those NIH programs that carry out their mission 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.

Program Official: The NIH Institute or Center official responsible for the programmatic, scientific and/or technical aspects of a grant.

Project Period: The total time for which support of a project has been programmatically approved. The total project period is comprised of the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and noncompeting 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."

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 Small Business Administration at 13 Code of Federal Regulations (CFR) Part 121.

State Government: The government of: any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. For purposes of NIH grants, federally recognized Indian tribal governments are generally considered State governments. State institutions of higher education and State hospitals are not considered State governments for purposes of the Department of Health and Human Services' general administrative requirements for grants and this policy statement.

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.

Substantial Foreign Component: Under a grant to a domestic institution, the performance of any significant element or segment of the project outside of the United States, either by the grantee or by a researcher employed by a foreign institution, with or without grant funds.

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.

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 Notice of Grant Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate postaward 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 facilities and administrative 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.

Withholding of Support: A decision by NIH not to make a noncompeting continuation award within the current competitive segment.

Acronyms and Abbreviations

CFR	Code of Federal Regulations
CSR	Center for Scientific Review
DCA	Division of Cost Allocation
EA	Expanded Authorities
F&A	Facilities and Administrative (costs)
FCTR	Federal Cash Transactions Report (SF-272)
FDP	Federal Demonstration Partnership
FSR	Financial Status Report (SF-269 or 269A)
GMO	Grants Management Officer
HHS	Department of Health and Human Services
IC	Institute or Center
NGA	Notice of Grant Award
NIH	National Institutes of Health
NIHGPS	National Institutes of Health Grants Policy Statement
NRSA	National Research Service Award
OER	Office of Extramural Research
OFM	Office of Financial Management
OIG	Office of the Inspector General
OMB	Office of Management and Budget
OPERA	Office of Policy for Extramural Research Administration
OPRR	Office for Protection from Research Risks
ORI	Office of Research Integrity
PA	Program Announcement
PI	Principal Investigator/Program Director/Project Director
PMS	Payment Management System
PO	Program Official
RFA	Request for Applications
SBIR	Small Business Innovation Research Program
SNAP	Streamlined Noncompeting Award Process
STTR	Small Business Technology Transfer Program

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 both within the Department of Health and Human Services (hereafter referred to as "HHS" or the "Department") and external to HHS.

NIH is an organizational component of HHS, the mission of which is to improve human health by increasing scientific knowledge related to disease and health. 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, nonprofit research organizations, for-profit organizations, and individuals). NIH also works closely with other HHS components[1] and other Federal departments and agencies.

NIH is organized into Institutes and Centers (ICs), each with its own mission and functions, separate appropriations, and statutory authorities. The ICs that award grants and their points of contact are listed in Part IV. Although these ICs operate under the same general grant process and requirements, there may be differences of which applicants and grantees need to be aware. This information may be obtained from NIH staff. The policies and procedures generally applicable to NIH grants are set forth in this NIH-wide policy statement.

At the Departmental level, HHS develops, issues, and maintains regulations that govern the HHS 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 Code of Federal Regulations (CFR) Part 92 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments) and 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)[2]. They provide the standard framework for the terms and conditions of NIH awards as specified in Part II.

Roles and Responsibilities

The relationship between NIH and its grantees involves those engaged in the scientific or technical aspects of the work as well as those responsible for a variety of support functions. 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

[1] These include the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS), the Agency for Health Care Policy and Research (AHCPR), the Health Resources and Services Administration (HRSA), the Administration for Children and Families (ACF), the Administration on Aging(AoA), and the Health Care Financing Administration (HCFA).

[2] 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.

separation of responsibilities within its own staff and by establishing a similar set of expectations for grantee operations. Although these roles and responsibilities are ones with which NIH grantees should already be familiar, they assume increasing importance as NIH shifts to a greater reliance on systems compliance and provides greater decision-making authority to grantees.

The following subsections highlight the major functions and areas of responsibility of Federal and grantee staff. 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 Government and the grantee. The responsibilities of those NIH staff members in the Center for Scientific Review (CSR) involved only in the initial peer review process are described in the "Application and Review Processes" section. The responsibilities of other offices, such as the Office for Protection from Research Risks, are described in Part II.

NIH and HHS Staff

Grants Management Officer: The Grants Management Officer (GMO) whose name appears on the Notice of Grant Award 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 is an employee of the NIH IC that makes the award and is responsible for the efforts of IC grants management specialists. The GMO also works closely with his or her counterparts in other NIH ICs and with the designated Program Official. 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 funds or to change the funding, duration, or other terms and conditions of award.

Grants Management Specialist: The Grants Management Specialist is an agent of the GMO and is assigned responsibility for the day-to-day management of a portfolio of grants.

Program Official: The Program Official is the IC employee responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. Program Officials' responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with CSR/IC Scientific Review Administrators; and postaward administration, including review of progress reports, participating in site visits, and other activities complementary to those of the IC GMO. The Program Official and the GMO work as a team in many of these activities.

Scientific Review Administrator: The Scientific Review Administrator (SRA) is a health science administrator that manages the activities of a scientific review group, including CSR study sections. The SRA performs an initial review of 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 scientific review group meeting.

Other NIH and HHS Staff: The grantee may be required to interact with other NIH or HHS staff/offices, in addition to the IC GMO and Program Official, with respect to its organization-wide systems and/or individual transaction(s). These include the office responsible for negotiation of F&A costs and research patient care rates, typically the cognizant (based on geographical location) HHS Division of Cost Allo-

cation office or the Office of Contracts Management, NIH[3]; the Division of Payment Management; the Office of the Inspector General; the Office for Protection from Research Risks, and the Office of Research Integrity. Staff 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 IV includes a list of these organizations and their addresses and telephone numbers.

Grantee Staff

Authorized Institutional Official: This official 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 or changes in award terms and conditions. In signing a grant application, this individual indicates the applicant organization's intent to comply with all applicable terms and conditions of award, including assurances and certifications referenced in the application, and attests to the fact that the administrative, fiscal, and scientific information in the application is true and complete and in conformance with governing Federal and organizational requirements. This individual's signature on the grant application further assures 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. (See also "Legal Implication of Application.") This individual is also responsible to NIH for ensuring that the organization complies with the terms and conditions of individual awards and organization-wide requirements, such as financial management and property management requirements. NIH does not specify the organizational location or full set of responsibilities for such an official; however, it requires the designation of such an official as the focal point for the organization's responsibilities as the grantee.

Principal Investigator: The principal investigator (PI) (may also be known as "program director" or "project director") is the individual, designated by the grantee, responsible for the scientific or technical aspects of the grant and day-to-day management of the project. The PI must have a formal written appointment with the applicant organization, which must be in the form of an official relationship between the parties, but need not involve a salary or other form of remuneration. The PI is a member of the grantee team responsible for ensuring compliance with the financial and administrative aspects of the award. He or she works closely with designated officials within the grantee organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; ensure that Federal support of research findings is appropriately acknowledged in publications, announcements, news programs, etc. (see "Administrative Requirements—Availability of Research Results: Publications and Intellectual Property, Including Unique Research Resources"); and comply with organizational as well as Federal requirements. NIH encourages the PI to maintain contact with the NIH Program Official with respect to the scientific aspects of the project. NIH also encourages the PI to maintain contact with the IC GMO concerning the business and administrative aspects of the award.

NOTE: The concept of co-principal investigators is not formally recognized by NIH. NIH staff conduct official business only with the designated PI and authorized institutional officials.

[3] The Office of Naval Research is the cognizant agency for negotiation of F&A costs for some NIH grantees.

Application and Review Processes

This subsection provides an overview of the types of grants NIH funds; the ways in which potential applicants can learn about funding opportunities; distinctions among types of applications; application requirements, restrictions, and deadlines; how applications are reviewed and by whom; how results are communicated; and applicant rights. It also lists publications and NIH Web sites that can be accessed for additional information concerning the NIH grants process and programs.

Support Mechanisms

NIH ICs make grant awards 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 at the end of this section to become knowledgeable about the variety of NIH grant support available and specific application requirements. Some of these distinctions are also significant for purposes of applying Parts II and III of this policy statement.

Eligibility

In general, NIH grants may be awarded to organizations that are domestic or foreign, public or private, and non-profit or for-profit. Eligible organizations include governments, institutions of higher education, hospitals, individuals and Federal institutions. Any special criteria for applicant eligibility or requirements concerning the qualifications of the principal investigator or other staff will be specified in the program solicitation, program guidelines, or other publicly available documents. Part III includes information on trainee and fellow eligibility.

Types of Applications

The following describes the most frequently used types of applications in the NIH grants process and the prefixes NIH uses to distinguish them. With the exception of the "noncompeting continuation application," all of the application types listed below are considered "competing," since they must compete through the peer review process for available funding with other applications submitted. The process and requirements for noncompeting applications are specified in Part II.

- **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.

- **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 in the 2-year period dating from submission of the original, unamended application.

- **Noncompeting Continuation Application (Type 5):** A request for funding for the second or subsequent budget period within an approved project period.

Funding Opportunities

The preponderance of applications submitted to NIH under the categories of research, and research training and fellowships are for investigator-initiated research and are considered "unsolicited" applications. NIH reviews such applications in three review cycles per year. The schedules for submission, review, and award of competing unsolicited applications are included in the application kit and on the NIH Home Page. Applicants are encouraged to contact the IC from which they plan to seek funding. See Part IV for a list of the IC contact points.

Preliminary contact with the IC is required if an applicant anticipates submitting a single unsolicited (investigator-initiated) application, whether a new, competing continuation, competing supplement, or amended grant application under any NIH support mechanism, with a proposed direct cost budget of $500,000 or more for any one year. This requirement 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. This contact should occur as early in the application development process as possible. Applicants that are uncertain about which IC to contact should contact the Division of Receipt and Referral, CSR (see Part IV). CSR will accept such applications for review only if an IC has agreed to accept the application for consideration and the applicant submits a letter to that effect, with the name of the authorizing IC official, with its application (see "The Peer Review Process" below). **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 Requests for Applications (RFAs) (see below) but such applications must be responsive to any budgetary limits stated in the relevant RFA 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* and take one of two forms. NIH uses "program announcements" (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 described above 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 same receipt dates, compete for funding with all other unsolicited applications, and are subject to the standard peer review process. PAs are also used for soliciting applications for programs such as the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, which issue announcements annually. Those applications must be received by the date(s) specified in the PAs.

A more targeted solicitation is the Request for Applications (RFA) which may be used to solicit:

- Grant applications in a well-defined scientific area;
- Research grant applications for a one-time competition;
- Construction grant applications; or
- Applications for cooperative agreements.

RFAs are stand-alone solicitations, and each will provide sufficient information to allow prospective applicants to determine whether to apply, including the amount of funding available, the number of awards anticipated, 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 the awardee 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 dates (i.e., deadlines). 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 kit, 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 must also demonstrate compliance (or intent to comply), through certifications 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. Public policy requirements and cost and administrative policies are detailed in Part II.

Application Forms

The required application forms vary by support mechanism and by the type of funding requested. The forms for competing applications are specified in Table 1. The application requirements for noncompeting awards are discussed in Part II.

These forms, other than those for the SBIR/STTR programs, are included in application kits maintained by an organization's office of sponsored research or business office. Application kits are also available from the Office of Extramural Outreach and Information Resources, Office of Extramural Research, NIH, at (301) 435-0714, e-mail at grantsinfo@nih.gov, or mail at the address listed in Part IV. Certain forms (rather than a complete application kit) are available electronically on the NIH Home Page (**http://www.nih.gov**). NIH does not distribute software for computer generation of the application.

The SBIR/STTR applications are included in the SBIR and STTR Phase I grant solicitations, which are available electronically on NIH's "Small Business Funding Opportunities" site on the NIH Home Page at **http://grants.nih.gov/grants/funding/sbir.htm**. A limited number of hard copies of the SBIR/STTR solicitations is produced. Subject to availability, they may be obtained from the PHS SBIR/STTR Solicitation Office, 13687 Baltimore Avenue, Laurel, MD 20707-5096, telephone: (301) 206-9385, fax: (301) 206-9722, or e-mail: a2y@cu.nih.gov. Each SBIR and STTR Phase I grantee (small business concern) is automatically sent a Phase II application package.

TABLE 1

REQUIRED FORMS FOR COMPETING APPLICATIONS		
APPLICATION TITLE	FORM NUMBER	USE
Application for a Public Health Service Grant	PHS-398	New, revised, competing continuation, and competing supplemental research project grants and cooperative agreements (other than those under the SBIR and STTR programs), program projects, centers, career development awards, Institutional National Research Service Awards (training grants), and conference grants
Application for Public Health Service Individual National Research Service Award	PHS-416-1	Competing applications for fellowships
Public Health Service Grant Application for Use by: State and Local Government Applicants and Nongovernmental Applicants for Health Services Projects	PHS-5161-1, including Standard Form (SF) 424, with budget and assurances applicable to nonconstruction (424-A and 424-B) or construction (424-C and 424-D)	State, local, and Indian tribal government applicants for all types of grants, and nongovernmental applicants for construction grants
Small Business Innovation Research (SBIR) Program Grant Applications	PHS-6246-1 PHS 6246-2	Competing applications--Phase I Competing applications--Phase II
Small Business Technology Transfer (STTR) Program Grant Applications	PHS-6246-3 PHS 6246-4	Competing applications--Phase I Competing applications--Phase II

Application Receipt Points and Deadlines

All competing applications, whether solicited or unsolicited, are required to be sent or delivered, in the number of copies specified in the application kit or solicitation, to the central NIH receipt point.[4] The address for that office is:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive, MSC 7710
Bethesda, MD 20892-7710

Preaddressed mailing labels are included in application kits.

If express mail or courier service is used, the zip code should be changed to 20817.

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 holiday, the date for receipt/mailing is extended to the next business day.

Under an RFA or a PA, if a solicitation-specific deadline date is included, an application received after the deadline date 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.

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 prior to receipt of the application.

[4] At the present time, NIH is participating with selected organizations in pilot efforts for electronic submission of applications.

Legal Implication of Application

The signature of an authorized institutional official on the application indicates the organization's intent to comply with the laws, regulations, and policies to which a grant is subject, including applicable public policy requirements (see "Public Policy Requirements and Objectives" in Part II). That official is also attesting to the fact that the information contained in the application is true and complete, and in conformance with Federal requirements and the organization's own policies and requirements. 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 Internal Revenue Service (IRS). The applicant is also expected to be in compliance with applicable State and local laws and ordinances.

Part II of this policy statement includes administrative remedies the Government may use in the event that a grantee or its employees submit fraudulent information or do not comply with applicable requirements. Even if a grant is not awarded, the applicant may be subject to penalties if the information contained in an application, including its assurances, is found to be false, fictitious, or fraudulent.

The Program Fraud and Civil Remedies Act of 1986, 31 United States Code (U.S.C.) 3801, 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 may be made in lieu of damages, up to $150,000.

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. Such person may be subject to imprisonment of not more than 5 years and a fine.

The Civil False Claims Act, 31 U.S.C. 2739, 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 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 Government provides or will reimburse any portion of the funds claimed. Civil penalties of $5,000 to $10,000 may be imposed for each false claim, plus damages of up to three times the amount of the false claim.

NIH may also 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 or information that is commercial or financial, or privileged or confidential, the pages containing that information should be identified as specified in the instructions provided in the PHS-398 application kit.

When information in the application constitutes trade secrets or information that is commercial or financial, confidential or privileged, it is furnished to the Government in confidence, with the understanding that the information shall 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 Freedom of Information 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 Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the 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 Web sites: **http://www.csr.nih.gov** and **http://grants.nih.gov/grants/peer/peer.htm**. Information is also available by e-mail at DRGINFO@drgpo.drg.nih.gov or grantsinfo @od.nih.gov, or by calling, writing, or faxing a request to CSR (see Part IV).

Initial Review

The Center for Scientific Review 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 Academic Research and Enhancement Award (AREA) applications), National Research Service Award (NRSA) 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. However, CSR may review other types of applications at IC request.

CSR Referral Officers, who are senior health science administrators with both research and scientific review experience, assign each application to an IC(s) for potential funding and to a scientific review group 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/IC assignment.

Scientific review groups, including CSR study sections, are organized by scientific discipline or current research areas and are managed by health scientist administrators functioning as Scientific Review Administrators. 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. Special Emphasis Panels (SEPs) are formed on an ad hoc basis 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.

Those individuals serving on a scientific review group, whether a study section or SEP, are primarily 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, scientific review group, and IC assignments. At this time, applicants may request reconsideration of the review group 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 review group 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 authorized institutional official. 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 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. NIH uses "just-in-time" procedures for certain programs and award mechanisms that call for limited budget information to be submitted with the application (i.e., a budget justification and a modified biographical sketch) and for a possible NIH request for additional information when the application is under consideration for funding. (Applications in response to RFAs may also be subject to these pro-

cedures. The RFA will specify the timing and nature of required submissions.)

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, and enhance health. Reviewers are asked to address, in their written comments, the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them, as appropriate, for each application. 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.

- 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 method? Are the aims original and innovative? Does the project challenge existing paradigms 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 institutional support?

While the review criteria are intended for use primarily with unsolicited research project grant applications (e.g., R01s and P01s), including those in response to PAs, to the extent reasonable, they will also 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, as stated, may not be feasible. Applications may also 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:

- The 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 will also be evaluated.

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

- The 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.

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.

Applicants responding to RFAs submit copies concurrently to CSR and the soliciting IC. 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.

National Advisory Council or Board Review

For those applications recommended for further consideration, the summary statements are presented to the assigned IC National Advisory Council or Board (hereafter "Council") for use in the second level of review. Council members include both 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 initial review group'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 initial review group 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 initial review group and the Council.

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 (*NIH Guide for Grants and Contracts*, Vol. 26, No. 38, November 21, 1997). This appeal process is not intended to deal with differences of scientific opinion between or among investigators and reviewers.

If the applicant has concerns about the conduct of the review, whether the initial review was conducted by CSR or by the IC, the applicant should discuss them with the program administrator responsible for the application, who will attempt to resolve the applicant's concerns. If, after discussion with the program administrator, the investigator still has concerns, he or she may submit a formal letter of appeal to the program administrator, who will handle it in accordance with specific appeal procedures.

The program administrator 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 NIH staff and the investigator 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 either reject the appeal and let the initial review stand or recommend that the application be re-reviewed. The Council's decision may not be further appealed.

Disposition of Applications

All incomplete applications and those applications determined to be non-responsive to solicitation requirements will be returned to the applicant by CSR or by the IC referral office without further action. For unsolicited applications that are returned, the applicant may resubmit a complete version of the 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 an additional cycle(s) 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), but NIH will not accept a revised application submitted more than 2 years from the receipt of the original application.

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 IC 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 appeals to any NIH or HHS official or board.

Sources of Information about NIH's Grants Process and Programs

As described below, NIH maintains a number of information resources about its grant programs and activities that can be accessed through the Home Page maintained by the Office of Extramural Research. Some are descriptive materials that allow interested parties to learn about NIH grant initiatives, funding opportunities, and proposed and actual policy changes. Others provide historical data. These documents are updated annually or as needed. The NIH Web site 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 using e-mail through grantsinfo@nih.gov, by telephone at (301) 435-0714, or by writing to the Office of Extramural Outreach and Information Resources, Office of Extramural Research, 6701 Rockledge Drive, Suite 6095, Bethesda, MD 20892-7910.

These information resources include:

***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 Web site address is **http://grants.nih.gov/grants/oer.htm.**

***NIH Guide for Grants and Contracts*:** announces new programs and policies, including program announcements, Requests for Applications, and Requests for Proposals. The Web site address for the NIH Guide is **http://grants.nih.gov/grants/oer.htm**.

***Research Grants and Contracts*:** annual listing of extramural awards, previously known as "the brown book." The Web site address is **http://grants.nih.gov/grants/award/award.htm**.

Computer Retrieval of Information on Scientific Projects (CRISP): an on-line system (**http://www-commons.dcrt.nih.gov**), updated quarterly, that provides a brief description of and administrative data on each NIH-funded research project.

Program Guidelines: 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 are also accessible by title at **http://www.nih.gov/grants/documentindex.htm**. IC Home Pages should also be consulted for IC-specific guidelines (see Part IV).

Other documents providing information about or general descriptions of NIH programs may also be requested. These include *Helpful Hints on Preparing a Research Grant Application to the NIH, Helpful Hints on Preparing a Fellowship Application to the NIH, Research Training and*

Career Development Programs, and *NIH Minority Programs*. These documents contain useful information but are not currently available on-line and may not provide as up-to-date or complete information as those documents linked to the NIH OER Home Page.

Each IC also maintains its own Home Page accessible through the NIH Home Page submenu entitled "Institutes and Offices" (see Part IV for current Web site addresses).

Part II: Terms and Conditions of NIH Grant Awards

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COMPLETING THE PREAWARD 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 (see below), review of the project budget, assessment of the applicant's management systems, and determination of applicant compliance with eligibility and public policy requirements. Based on the outcome of these reviews, the IC will determine whether an award can be made, if special conditions are required, and the appropriate level of funding.

Although these reviews and determinations are initially made prior to the issuance of 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 preaward process for noncompeting continuation applications is a streamlined version of this process, including an assessment of progress (see "Administrative Requirements—Noncompeting Continuation Awards").

Funding Principles

NIH awards grants on the basis of reasonable and allowable costs consistent with the principles of sound cost management and in consideration of IC priorities (e.g., program relevance), constraints on the growth of average grant costs, and available funds.

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

- NIH will award noncompeting research project grants at committed levels.
- Determination of commitments for future years must take into consideration 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 would be 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 through documentation or by signing a certification (e.g., a small business applying under the SBIR or STTR programs).

In addition to reviewing applicants' organizational eligibility, NIH may consider other eligibility 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, where the project will be performed, the role of the PI in the project, and his/her employment and citizenship status. Although some of these same considerations are reviewed as part of the peer review, at this stage in the process NIH's concern is making an award to a legal entity that will be accountable both for 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 IC GMO will also verify whether the applicant, proposed PI, or other key personnel are debarred or suspended from participation in Federal assistance programs, and whether the applicant is delinquent on the repayment of any Federal debt (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and

Organizational Operations" for certification requirements).

Although PIs and other personnel under research projects are not required to be U.S. citizens, NIH will not intercede on behalf of non-citizens whose stay in the United States may be limited by their visa status. As a result, NIH requires the applicant to determine and indicate, in its application, that such individuals' visas will allow them to remain in this country long enough for them to be productive on the project. If a grant is awarded on the basis of this information and the individual's visa does not allow for such a stay, 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 fellows are addressed in "National Research Service Awards" in Part III.

NIH continues its oversight of eligibility considerations, from both a legal and programmatic perspective, in the postaward phase by monitoring changes in grantee and project status and taking 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 includes 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, the complexity of the project, prior experience with the applicant, and other factors. Detailed information on the applicable cost principles and on allowable and unallowable costs under NIH grants is provided in "Cost Considerations" in this Part.

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 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

Parts II and III of this policy statement are the terms and conditions of NIH grants and cooperative agreements and will be incorporated by reference in all NIH awards as specified in "Introduction—Background and Supersession." These terms and conditions are not intended to be all-inclusive. In addition to the requirements included in this policy statement, NIH grants are subject to the requirements of:

- The authorizing program legislation;
- Program regulations, including those at 42 CFR Part 52;
- Other statutory requirements, such as those included in appropriations acts; and
- HHS requirements in 45 CFR Part 74 or 92, as appropriate for the type of recipient organization and the type of activity (e.g., research).

Notice of these latter requirements will generally be provided in the Notice of Grant Award (NGA), but such notice is not required in order for the award to be subject to the requirements of pertinent statutes and regulations. An individual award may also 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 this policy statement apply in addition to governing statutory and regulatory requirements, and award-specific terms apply in addition to the requirements of this policy statement.

This policy statement is 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, if there is a perceived conflict between or among these three categories of requirements; i.e., statutory and regulatory requirements, this policy statement, 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 IC 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 as interpreted and applied by the awarding office.

PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

The following subsections deal with 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 and contractors, in general, or may relate to the expenditure of Federal funds for research or other specified activities, in particular. In addition to cross-cutting requirements that apply to Federal agencies and their grant programs, NIH grantees are subject to requirements contained in NIH's annual appropriations acts that apply to the use of NIH grant funds. 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 below set many of those standards. The signature of the authorized official on the application indicates that the organization is in compliance with, or intends to comply with, these requirements. Applicants and grantees should take particular note of requirements for assurances or certifications, the absence or inadequacy of which may delay an award or make an applicant ineligible for award. In general, assurances are required on a one-time basis, with updating or changes as necessary, and certifications are required annually and are accomplished by the authorized institutional official's signature on the application (see discussion of individual requirements below).

The grantee is responsible for establishing and maintaining the necessary processes to monitor its compliance and that of its employees 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.

The HHS Inspector General (IG) maintains a post office box and a toll-free hotline for receiving information from individuals concerning fraud, waste, or abuse under HHS grants and cooperative agreements. This information is kept confidential, and callers are not required to give their names. The address and telephone number are included in Part IV.

Table 2 is provided to assist the grantee in determining the applicability of particular public policy requirements and objectives to its own activities as well as in determining whether to include a requirement in a consortium agreement or a contract for routine purchased goods or services under the grant (see "Glossary" for definitions). The table distinguishes between these types of transactions under a grant and indicates whether a given public policy requirement would normally apply. However, even if the table indicates a requirement is "Not Applicable," that public policy requirement could potentially be applicable in a specific situation; e.g., if a contract under a grant involves research activity. Therefore, this table should be used as general guidance only. The grantee should consult the terms and conditions of its award and contact the awarding office GMO if there is any question concerning the applicability of a particular public policy requirement or objective.

The listing in Table 2 provides summary information on each requirement and indicates where, in this policy statement, it is covered in more detail. However, the governing statute, regulations, or other cited policies or documents should be consulted for complete information.

TABLE 2

PUBLIC POLICY REQUIREMENTS AND OBJECTIVES				
Requirement or Objective	Grantee	Consortium Participant	Contractor under Grant (Routine Goods/Services)*	GPS Section for Additional Information
Acknowledgment of Federal Funding	X	X	N/A	Part II—Availability of Information Part III—National Research Service Awards
Age Discrimination Act of 1975	X N/A to foreign and international organizations	X N/A to foreign and international organizations)	X N/A to foreign and international organizations	Part II—Civil Rights Part III—National Research Service Awards; Awards to Foreign Institutions, International Organizations and Domestic Grants with Substantial Foreign Components (hereafter, in this Table, Awards to Foreign Institutions)
Animal Welfare	X	X	X	Part II—Animal Welfare Part III—National Research Service Awards; Awards to Foreign Institutions
Ban on Human Embryo Research and Cloning	X	X	X	Part II—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients or Recipients of Services (hereafter, in this Table, Requirements Affecting the Rights and Welfare of Individuals)
Civil Rights Act of 1964 (Title VI)	X N/A to foreign and international organizations	X N/A to foreign and international organizations	X N/A to foreign and international organizations	Part II—Civil Rights Part III—National Research Service Awards; Awards to Foreign Institutions
Confidentiality of Patient Records	X	X	X	Part II—Requirements Affecting the Rights and Welfare of Individuals
Conflict of Interest	X (42 CFR Part 50 N/A to SBIR/STTR Phase I)	X	N/A	Part II—Ethical and Safe Conduct in Science and Organizational Operations
Controlled Substances	X	X	X	Part II—Requirements Affecting the Rights and Welfare of Individuals
Debarment and Suspension	X (N/A to certain foreign organizations)	X (N/A to certain foreign organizations)	If contract equals or exceeds $100,000; N/A to certain foreign organizations	Part II—Ethical and Safe Conduct in Science and Organizational Operations Part III—Awards to Foreign Institutions
Drug-Free Workplace	X	N/A	N/A	Part II—Ethical and Safe Conduct in Science and Organizational Operations Part III—Awards to Foreign Institutions

TABLE 2 (Continued)

PUBLIC POLICY REQUIREMENTS AND OBJECTIVES				
Requirement or Objective	Grantee	Consortium Participant	Contractor under Grant (Routine Goods/Services)*	GPS Section for Additional Information
Education Amendments of 1972 (Title IX)	X (N/A to foreign and international organizations	X (N/A to foreign and international organizations)	X (N/A to foreign and international organizations)	Part II—Civil Rights Part III—National Research Service Awards; Awards to Foreign Institutions
Elimination of Architectural Barriers to the Handicapped	X	N/A	X	Part III—Construction Grants
Flood Insurance	X	N/A	NA	Part III—Construction Grants
The Freedom of Information Act	Applies to covered material in NIH's possession	Applies to covered material in NIH's possession	Applies to covered material in NIH's possession	Part II—Availability of Information
Health and Safety Guidelines	X	X	Applies as required by Federal, State or local regulations	Part II—Ethical and Safe Conduct in Science and Organizational Operations
Historic Properties/ Archeological Sites	X	N/A	X	Part III—Construction Grants
Human Subjects	X	X	X	Part II—Requirements Affecting the Rights and Welfare of Individuals Part III—National Research Service Awards; Awards to Foreign Institutions
Inclusion of Children as Subjects in Clinical Research	X	X	N/A	Part II—Requirements for Inclusiveness in Research Design Part III—National Research Service Awards; Awards to Foreign Institutions
Inclusion of Women/Minorities as Subjects in Clinical Research	X	X	N/A	Part II—Requirements for Inclusiveness in Research Design Part III—National Research Service Awards; Awards to Foreign Institutions
Intergovernmental Review under EO 12372	X	N/A	N/A	Part III—Construction Grants
Investigational New Drug Applications	X	X	X	Part II—Requirements Affecting the Rights and Welfare of Individuals
Labor Standards under Federally Assisted Construction	X	N/A	X	Part III—Construction Grants

TABLE 2 (Continued)

PUBLIC POLICY REQUIREMENTS AND OBJECTIVES				
Requirement or Objective	Grantee	Consortium Participant	Contractor under Grant (Routine Goods/Services)*	GPS Section for Additional Information
Limitation on Use of Funds for Promotion or Legalization of Controlled Substances	X	X	X	Part II—Ethical and Safe Conduct in Science and Organizational Operations
Lobbying	Certification required if total costs expected to exceed $100,000	Certification required if greater than $100,000 only	Certification required on contracts greater than $100,000 only	Part II—Ethical and Safe Conduct in Science and Organizational Operations
Metric System	X	X	X	Part II—Other Public Policy Requirements and Objectives Part III—Construction Grants
Military Recruiting/ROTC Program Access to Institutions of Higher Education	X	X	X	Part II—Other Public Policy Requirements and Objectives
Misconduct in Science	X	X	N/A	Part II—Ethical and Safe Conduct in Science and Organizational Operations Part III—Awards to Foreign Institutions
National Environmental Policy Act of 1969	X	N/A	N/A	Part III—Construction Grants
Nondelinquency on Federal Debt	X	Applies to individuals as participants	N/A	Part II—Ethical and Safe Conduct in Science and Organizational Operations Part III—Awards to Foreign Institutions
The Privacy Act	Applies to covered material in NIH's possession	Applies to covered material in NIH's possession	Applies to covered material in NIH's possession	Part II—Availability of Information
Pro-Children Act of 1994	X	X	X	Part II—Requirements Affecting the Rights and Welfare of Individuals
Program Fraud and Civil Remedies and False Claims Acts	X	X	N/A	Part I—Application and Review Processes—Legal Implication of Application
Protection of Research Subjects' Identity	X	X	X	Part II—Requirements Affecting the Rights and Welfare of Individuals

TABLE 2 (Continued)

PUBLIC POLICY REQUIREMENTS AND OBJECTIVES				
Requirement or Objective	Grantee	Consortium Participant	Contractor under Grant (Routine Goods/Services)*	GPS Section for Additional Information
Public Disclosure	X	N/A	N/A	Part III—Construction Grants
Recombinant DNA and Institutional Biosafety Committees	X	X	X	Part II—Ethical and Safe Conduct in Science and Organizational Operations Part III—National Research Service Awards
Rehabilitation Act of 1973 (section 504)	X (N/A to foreign and international organizations)	X (N/A to foreign and international organizations)	X (N/A to foreign and international organizations)	Part II—Civil Rights Part III—National Research Service Awards; Awards to Foreign Institutions
Relocation Assistance and Real Property Acquisition	X	N/A	N/A	Part III—Construction Grants
Research on Transplantation of Fetal Tissue	X	X	X	Part II—Requirements Affecting the Rights and Welfare of Individuals
Restriction on Distribution of Sterile Needles	X	X	X	Part II—Ethical and Safe Conduct in Science and Organizational Operations
Seat Belt Use	X	N/A	N/A	Part II—Ethical and Safe Conduct in Science and Organizational Operations
Smoke-Free Workplace	X	N/A	N/A	Part II—Ethical and Safe Conduct in Science and Organizational Operations
Year 2000 Compliance	X	X	X	Part II—Other Public Policy Requirements and Objectives

*A designation of N/A 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 organizations are responsible in their handling of Federal awards, and to minimize the opportunity for improper financial gain on the part of grantees and their employees and 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.

Conflict of Interest

Grantees must 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 must also:

- 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 institutional official;
- Include a process for notification and review by the responsible official of potential or actual violations of the standards; and
- Specify the nature of penalties that the grantee may impose. These penalties would be in addition to any penalties that may be imposed by NIH or a cognizant Federal agency 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 officer of the grantee, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, the NIH awarding office. The grantee is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and informing NIH if the infraction is related to an NIH award. If a suspension or separation action is taken by a grantee against a PI or other key personnel under an NIH grant, the IC GMO must be notified as specified in "Administrative Requirements—Changes in Project and Budget."

NIH also 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 NIH Funding is Sought," pertaining to investigators' actual or potential financial conflicts of interests. These requirements do not apply to grants under Phase I of the SBIR/STTR programs.

The signature of the authorized organizational official on the face page of the application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F, including that:

- There is in effect, at that organization, a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought;

- Prior to the expenditure of any NIH funds awarded under a new award, the organization will inform NIH of the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 it identified and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations;

- It will continue to make similar reports on subsequently identified conflicts; and

- It will make information available to NIH, upon request, as to how identified conflicting interests have been handled.

Debarment and Suspension

HHS regulations published at 45 CFR Part 76 implement the government-wide debarment and suspension system for HHS's nonprocurement transactions. "Nonprocurement transactions" include grants, cooperative agreements, scholarships, fellowships, and loans. Accordingly, applicants for NIH grants ("primary covered transactions") are required to certify[1] 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, commission of 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, for violation of a Federal or State antitrust statute; for commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, or for 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. The full text of the instructions and the certification are included in Appendix A to 45 CFR Part 76.

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 neither they nor their principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal agency, and, if unable to certify, the grantee must attach an explanation to the application or provide the information to the GMO prior to awarding the contract or entering into the agreement.

Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) requires that all grantees receiving grants from any Federal agency agree that they will maintain a drug-free workplace. By signing the applica-

[1] This certification is provided as part of the application form. States need only complete this certification as to their principals.

tion, the authorized institutional official agrees that the grantee will provide a drug-free workplace and will comply with requirements to notify NIH in the event that 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, "Government-wide Debarment and Suspension (Nonprocurement)and Government-wide Requirements for Drug-Free Workplace (Grants)."

Health and Safety 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. The following standards and guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities, and they serve to supplement prevailing Federal, State, and local laws and regulations:

- *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Institutes of Health. HHS Publication No. (CDC) 93-8395. This publication is available at **http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm**.

- 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. Copies of these regulations may be obtained from OSHA Office of Publications, U.S. Department of Labor, Room N3101, 200 Constitution Avenue, NW, Washington DC 20210; telephone: (202) 219-4667.

- *Prudent Practices for Safety in Laboratories (1995)*, National Research Council. National Academy Press, 2101 Constitution Avenue, NW, Lockbox 285, Washington, DC 20418; telephone: 1-800-624-6242.

- 42 CFR Part 72, *Interstate Shipment of Etiological Agents*, and, in particular, 72.2, Additional Requirements for Facilities Transferring or Receiving Select Agents. Copies of these regulations are available from the Office of Health and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333; telephone: (404) 639-2453.

- *Procedures for Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents*, 1994 (3rd ed.), H5a3doc.75, National Committee for Clinical Laboratory Standards. Copies may be obtained from NCCLS Ordering Department, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898; telephone: (610) 688-6400.

- 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.

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

Limitation on Use of Funds for Promotion or Legalization of Controlled Substances

NIH officials 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 it is made known to the Federal official having authority to obligate funds, in this case 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" in this section).

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 Federal (appropriated) 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, that 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, they will be responsible for reporting the use of non-appropriated funds for such purposes, and they 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 authorized institutional official on the application serves as the required certification of compliance. 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 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. See also "Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost."

Misconduct in Science

The grantee will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent misconduct in science. Regulations at 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," specify grantee responsibilities in dealing with and reporting possible misconduct in science. Organizations applying for or receiving NIH research grants are required to certify in their applications that they have 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 Office of Research Integrity (ORI) on its home page (**http://www.ori.dhhs.gov**) and, in hard copy, at the address shown in Part IV.

As stated throughout this NIH GPS, the primary responsibility for ensuring that an NIH-funded project is being conducted in accordance with the approved application and budget and the terms and conditions of the award rests with the grantee. These responsibilities must be carried out with extra care where misconduct in science has been found or where a misconduct in science investigation has been initiated, as specified in 42 CFR 50.103 and 50.104. The grantee shall report promptly to ORI any incident of alleged or apparent misconduct in science 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").

Where 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(s), protect human subjects and animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the conduct of the investigation, if appropriate. ORI staff are available to assist grantees with respect to misconduct in science investigations and reporting, and IC staff are available to provide technical assistance and to work jointly with grantees to protect funded projects from the adverse effects of misconduct in science.

When a finding of misconduct in science has been made regarding conduct by an individual(s) working on an NIH grant-supported project, the grantee must assess the effect of that finding on the ability to continue that project, as originally approved by NIH, and promptly obtain NIH approval of any intended change of PI or other key personnel. A finding of misconduct in science may result in a range of possible sanctions by NIH, including, but not limited to, withdrawal of approval of the PI or other key personnel, debarment, disallowance of costs associated with the invalid or unreliable research, withholding of all or part of a continuation award, and/or suspension or termination, in whole or in part, of the current award. These actions are described in "Administrative Requirements—Enforcement Actions."

The grantee is responsible for the actions of its employees and other research collaborators involved in the project. Where the validity or reliability of data has been affected by misconduct in science, the grantee and its employee/collaborator authors are responsible for submitting a correction or retraction of the data to a journal, as appropriate, and/or publishing the corrected data, if required. Corrections or retractions may be required by ORI or NIH. 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.

Issues involving potential criminal violations, such as misappropriation of Federal funds, must be promptly reported to the HHS Office of the Inspector General (see Part IV).

Nondelinquency on Federal Debt

The Federal Debt Collection Procedure 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. Before a grant can be awarded, the applicant organization must certify that neither it nor any person to be paid from grant funds is delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal Government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or satisfactory arrangements made, NIH will still 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 NIH support 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.

Recombinant DNA and Institutional Biosafety Committees

All research involving recombinant DNA techniques that is supported by NIH must meet the requirements of *the NIH Guidelines for Research Involving Recombinant DNA Molecules* (the Guidelines) (59 FR 34496, July 5, 1994 or latest revision). As defined by the 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) DNA molecules that result from the replication of those described in (1).

Each institution that conducts (or will conduct) research involving recombinant DNA technology, including contractors under grants, must establish a standing Institutional Biosafety Committee. The composition requirements of these committees are specified in section IV of the Guidelines, which also discusses the roles and responsibilities of PIs and grantees. The committee is required to review each proposed nonexempt project for recombinant DNA experiments and certify that it has found the procedures, project, personnel, and facilities adequate and in compliance with the Guidelines. A roster of the members of the Institutional Biosafety Committee must be submitted to the Office of Recombinant DNA Activities (see Part IV for address). At a minimum, the roster should include the names, addresses, occupations, and qualifications of the chairperson and members of the committee.

The Guidelines, available from the Office of Recombinant DNA Activities, should be consulted for complete requirements for the conduct of projects involving recombinant DNA technology, including requirements for submission of information to other Federal agencies, such as the Food and Drug Administration.

Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to carry out any program involving distribution of sterile needles or syringes for the hypodermic injection of any illegal drug unless the Secretary, HHS, determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, and the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and ensuring that the project does not encourage the use of illegal drugs.

Seat Belt Use

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

Smoke-Free Workplace

NIH strongly encourages all recipients of its grants to provide smoke-free workplaces and promote the nonuse of tobacco products. NIH defines the term "workplace" to mean office space (including private offices and other work space), 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

Ban on Human Embryo Research and Cloning

NIH appropriated 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(s) for research purposes or for research in which a human embryo(s) 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 46.208(a)(2) and section 498(b) of the PHS Act. The term "human embryo(s)" 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 section 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.

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 at 42 CFR Parts 2 and 2a.

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 requirements of the Drug Enforcement Administration (DEA), 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 (202) 254-8255. Information is also available from the National Institute on Drug Abuse at (301) 443-6300.

Human Subjects

HHS regulations for the protection of human subjects, at 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. They stipulate that the applicant/grantee, whether domestic or foreign, is responsible for safeguarding the rights and welfare of human subjects involved in NIH grant-supported research activities. Subpart A of the HHS regulations constitutes the Federal policy (common rule) for the protection of human subjects.

Applicant organizations proposing to involve human subjects in nonexempt research must file (or have previously filed) a written Assurance of Compliance with the Office for Protection from Research Risks (OPRR) setting forth the commitment of the organization to establish appropriate policies and procedures for the protection of human subjects. Affiliated organizations or organizations that will serve as other performance sites for the grant-supported research must also file an Assurance. OPRR is responsible for approving the Assurance, which may be a Multiple Project Assurance (MPA), a Single Project Assurance (SPA), or other type of Assurance, as

appropriate. OPRR may also negotiate an Inter-Institutional Amendment if employees of an organization with an MPA routinely conduct their grant-supported research at an affiliated institution, thereby avoiding the need for an SPA for each separate project performed at such sites.

NIH will not award any grant for nonexempt research involving human subjects unless the organization is operating under an approved Assurance and, if operating under an MPA, provides certification, as part of its application, that an appropriate Institutional Review Board (IRB) has, within 12 months of the budget period start date, reviewed and approved the proposed activity in accordance with the regulatory requirements. SPA organizations must provide certification of IRB approval to OPRR as part of the SPA. In addition, no human subjects may be involved in research at an affiliated institution prior to approval by OPRR of an applicable Assurance for that organization. If an MPA organization submits an application with the knowledge that human subjects may be involved within the project period, but definite plans are not set forth in the application, the research activity must be reviewed and approved by an IRB and a certification submitted to NIH before human subjects may be involved in covered research activities supported by the award.

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

- 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;
- Where 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; and
- Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged, appropriate additional safeguards are included in the study to protect the rights and welfare of these subjects.

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

No individual may receive NIH grant funds for covered research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an applicable written Assurance or the individual makes other arrangements with OPRR.

For purposes of this public policy requirement, the definitions at 45 CFR 46.102 apply. A "human subject" is defined as 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. The regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR 46.

"Research" is defined as "systematic investigation designed to develop or contribute to generalizable knowledge." Unless an activity is "exempt" (see 45 CFR 46.101), any activity meeting the regulatory definition of "research" constitutes research for purposes of applying the regulations, even if supported by a grant that might have as its overall purpose an activity that is not primarily research. (For example, some training programs may include research activities.) OPRR should also be consulted if there is any question concerning the classification of research as exempt or nonexempt.

Information concerning the preparation and negotiation of Assurances, as well as copies of the regulation, may be obtained from OPRR at the address shown in Part IV or from its home page at **http://grants.nih.gov/grants/oprr/oprr.htm**. OPRR has also produced a publication available through the Government Printing Office[2] and an instructional videotape.

Investigational New Drug Applications

All clinical research involving investigational new drugs (IND), drugs approved for a different indication, or experimental combinations of drugs, must meet the Food and Drug Administration's (FDA) IND regulations, FDA's human subjects protection requirements, and the HHS human subjects' requirements (as described above) to be eligible for funding.

The official sponsor of the IND, whether NIH, a grantee, or a third party, is legally responsible for meeting the FDA IND requirements. If a third party, such as a pharmaceutical company or research organization under contract to a grantee or to a pharmaceutical company, is the IND sponsor, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the IND sponsor rather than the grantee, which will generally be the case for larger, multi-site clinical trials. If the grantee is the IND holder, commonly referred to as an "investigator-initiated IND," the grantee or the investigator serves as the IND 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 IND requirements.

Following the filing of an IND, FDA has a 30-day period in which to review the IND. FDA may allow the IND to proceed or may defer approval of the IND until changes it deems acceptable are made. FDA may also order a clinical trial to be suspended or terminated, at any time, based on information it receives about that clinical trial. The FDA regulations are published at 21 CFR Parts 50 and 312.

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 (Act), 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 and 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 and 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 re-

[2] *Protecting Human 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 OPRR's Web site.

deemed. 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. Therefore, NIH does not require a separate certification of intent to comply with the Act. The signature of the applicant's authorized official will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH grant should be directed to the IC GMO.

Protection of Research Subjects' Identity

Section 301(d) of the PHS Act provides that the Secretary may authorize persons 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. Authorized persons may not be compelled to disclose subjects' identities in any Federal, State, or local civil, criminal, administrative, legislative or other proceeding. An applicant may request a certificate of confidentiality to protect research subjects' identities under a specific research project. The request should be submitted to the IC GMO, and, subject to IC review and approval, a certificate may be issued pursuant to 42 CFR 2a.

Research on Transplantation of Fetal Tissue

In submitting an application to NIH, the authorized institutional official 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 Secretary, HHS, 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 human subjects in research requirements specified above.

Animal Welfare

The *PHS Policy on Humane Care and Use of Laboratory (*the Policy) requires that applicant organizations proposing to use vertebrate animals in NIH-supported activities file a written Animal Welfare Assurance with the Office for Protection from Research Risks (OPRR), NIH. The Policy, which defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes," stipulates that the applicant/grantee bears responsibility for the humane care and use of animals in NIH-supported research activities. The Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires the applicant to establish appropriate policies and procedures for humane care and use of animals, based on the *NIH Guide for the Care and Use of Laboratory Animals*, and to comply with the Animal Welfare Act and its implementing regulations. This includes appointment of an Institutional Animal Care and Use Committee (IACUC) with specified responsibilities.

No NIH award for research involving live vertebrate animals will be made 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. Applications from organizations with approved Assurances will be considered incomplete if they do not include verification of IACUC review or do not contain the information concerning the use of vertebrate animals required as part of the application's research plan (see instructions for completion of the PHS-398 for the five specific points that need

to be addressed). In the case of apparent or potential violations of the Policy, NIH may refer applications back to the applicant for further IACUC review.

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. 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 OPRR.

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. 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 concerning the preparation and submission of Animal Welfare Assurances as well as copies of the Policy and other relevant materials are available from the Division of Animal Welfare, OPRR.

Requirements for Inclusiveness in Research Design

NIH has adopted policies requiring grant-supported research projects to be as inclusive in design as possible in order 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

Research involving human subjects of any age must comply with the *NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (NIH Guide for Grants and Contracts*, Vol. 23, No. 11, March 18, 1994, and *Federal Register*, 59 FR 14508-14513, March 28, 1994), implementing section 492B of the PHS Act. These guidelines require that women and members of minority groups and their subpopulations be included in any NIH-supported 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 child-bearing potential should not be routinely excluded from participation in clinical research; i.e., any biomedical or behavioral research involving human subjects. The guidelines should be reviewed for policy concerning inclusion of these groups in Phase III clinical trials.

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 noncompeting continuation request or other annual progress reporting (see "Administrative Requirements—Monitoring—Reporting").

Inclusion of Children as Subjects in Clinical Research

NIH has developed a separate policy on inclusion of children as subjects in clinical research that is similar to the policy regarding inclusion of women and minorities (see above). Any new application involving human subjects research submitted for a receipt date after October 1, 1998 must include children (i.e., individuals under the age of 21) 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. This policy applies to both exempt and nonexempt research

activities (see "Human Subjects" in this section). The inclusion of children as subjects in research must comply with all applicable provisions of 45 CFR Part 46 and other pertinent Federal laws and regulations. This policy is not mandatory for awards made prior to October 1, 1998 and for new applications submitted for earlier receipt dates.

Civil Rights

Before an NIH IC may make an award to any domestic applicant organization, the organization must affirm that it has an Assurance of Compliance with the statutes described below on file with the Office of Civil Rights (OCR), Office of the Secretary, HHS. The Assurance, Form HHS-690, is filed on an institutional basis and is not required for each application; however, the certification is required with each application. If the application has been recommended for funding and the applicant organization does not have an Assurance on file, it will receive, from the responsible IC, the required form and instructions for completion and submission. The Form HHS-690 is also available from grantsinfo@nih.gov or by telephone at (301) 435-0714.

Domestic organizations that receive funding from grantees rather than directly from NIH, including contractors under grants, are also required to file this Assurance, and the applicant/grantee is responsible for determining whether those organizations have the required Assurance on file or, 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 U.S. 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 U.S. 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.

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" in Part III. However, they may also apply to alteration and renovation (A&R) activities. A grantee undertaking an A&R project under a non-construction award should consult the GMO concerning potential applicability.

Availability of Information

With the exception of certain types of information that may be considered proprietary or private information that cannot be released, after the

grant is funded, most grant-related information submitted to NIH by the applicant or grantee in the application or postaward phase is considered public information and 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 makes information about awarded grants, including project title, the name of the PI, and the amount of the award, available to the public through the NIH Computer Retrieval of Information on Scientific Projects (CRISP) system. The project description provided by an applicant for a funded research grant application is sent to the National Technical Information Service (NTIS), U.S. Department of Commerce, where the information is used for dissemination of scientific information and scientific classification and program analysis purposes. The public may request these descriptions from NTIS. Other information may be released on a case-by-case basis as provided below.

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 and Intellectual Property Rights, Including Unique Research Resources" and elsewhere in this policy statement. The disclosure requirement stated below ("Acknowledgment of Federal Funding") is included in HHS appropriations statutes and applies government-wide.

Acknowledgment of Federal Funding

All grantees must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations, 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 (FOIA), 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 do not require grantees or contractors under grants to permit public access to their records. The regulations also indicate types of information that are generally exempt from release.

The following types of material will generally be released:

- Funded applications;
- Pending and funded noncompeting continuations;
- Grant progress reports; and
- Final reports of any audit, survey, review, or evaluation of grantee performance that have been transmitted to the grantee.

This includes information of this type maintained in electronic format.

The following types of records or information will generally be withheld in response to an FOIA request:

- Pending competing grant applications;
- Unfunded new and competing continuations and competing supplemental applications;
- Financial information regarding a person, such as salary information pertaining to project personnel;

- Information pertaining to an individual, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

- Predecisional opinions in interagency or intra-agency memoranda or letters expressed by 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; and

- Patent or other valuable commercial rights of the person or organization.

If NIH has substantial reason to believe that information in its records could reasonably be considered exempt, before the information is released in response to an FOIA request, the applicant or grantee will be notified of the request by the appropriate NIH FOIA office, through the PI, and will be given an opportunity to identify potentially patentable or commercially valuable information that should not be disclosed. After NIH consideration of the grantee's response, if any, the grantee will be informed of the agency's decision as to what documents will be released and to whom. If a document contains both disclosable and nondisclosable information, the nondisclosable information will be deleted by a designated NIH or HHS FOIA Officer, and the balance of the document will be disclosed.

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, as identified by the Act (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 grant records in the possession of NIH and include appropriate routine uses of such information. They also include requirements for safeguarding the records and for record retention and disposal.

In considering a request for information concerning an individual made by a party other than that individual, NIH must take into account both the requester's right to know under FOIA and the individual's right to privacy under the Privacy Act.

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 Executive Order 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 Part III 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 Parts 23 and 216, that precludes grant awards to schools that the Department of Defense (DOD) determines have an anti-ROTC (Reserve Officer Training Corps) 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 purposes. 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 makes its determination of ineligibility 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.

Year 2000 Compliance

As part of their responsibilities for the scientific, administrative, and financial aspects of the grant-supported activity, grantees are responsible for taking all steps necessary to anticipate and mitigate potential problems that might be caused by the advent of the Year 2000. NIH grantees are expected to ensure that the NIH activity being supported is not adversely affected by the Year 2000 problem, including any applicable computer systems, software applications, databases, and equipment.

All electronic data submitted to NIH by grantee organizations must be Year 2000 compliant. Data that is noncompliant will not be accepted. Organizations exchanging electronic data with NIH will also need to be able to interface with the systems being developed by NIH under its Electronic Research Administration (ERA) initiative. Further information may be obtained from the Inventions and Extramural Reporting Branch, the designated focal point in OPERA (see Part IV), and at **http://grants.nih.gov/grants/oer.htm**.

THE NOTICE OF GRANT AWARD

During the review process, the applicant may be asked to submit additional information or to undertake certain activities (such as negotiation of a facilities and administrative (F&A) rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made.

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 HHS payment system. An NGA is issued for the initial budget period and reflects future year commitments, if applicable. A revised NGA may be issued to effect an action resulting in a change in the period or amount of support or other change(s) in the terms and conditions of award. NIH will not issue a revised NGA to reflect a grantee's postaward 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—Preaward (Preagreement) Costs" for NIH policy on allowability of preaward costs).

The NGA sets forth pertinent information regarding the grant, including, but not limited to, the following:

- Application/grant identification number ("grant number"),
- Name of grantee institution,
- Name of the PI,
- The approved project period and budget period start and end dates,
- The amount of funds authorized for obligation by the grantee,
- The amount of anticipated future-year commitments (if applicable),
- The names of the cognizant IC Program Official and GMO, and
- 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 funds from the designated payment system. 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 or take other appropriate action to terminate the award. 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 (postaward 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 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 IC 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 IC's programmatic determination of the frequency of competitive review desirable for managing the project, and the NIH funding principles. The total project period consists of the initial competitive segment, any additional competitive segment(s) authorized by a competing continuation award(s), and any noncompeting extensions. NIH policy

limits each competitive segment to a maximum of 5 years (exclusive of noncompeting extensions). A single award covering the entire period of support is generally used only if the project is exclusively for construction or alteration or renovation of real property, the total planned period of support will be less than 18 months, or the project is awarded under a special support mechanism.

The initial grant award provides funds for the conduct of the project during the first budget period. Budget periods are usually 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 levels of future support) expresses NIH's intention to provide continued financial support to 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 expiration date of the current budget period as shown in the NGA.**

Grantees are required to submit a noncompeting continuation application as a prerequisite to NIH approval and funding of each subsequent budget period within an approved project period (see "Administrative Requirements—Noncompeting Continuation Awards"). 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 will also 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 will set forth the amount of funds awarded. The amount may be shown either as a line item budget or as an amount for total direct costs (not broken down by category) and an amount for total F&A costs. 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" in Part III.

Additional Terms and Conditions

In addition to, or in lieu of, the standard terms and conditions of award specified in this policy statement, 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. 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/Automated Clearinghouse (ACH), CASHLINE/ACH, or by monthly cash request on an advance or reimbursement basis, as specified in the NGA and as described below. Payments under NIH grants are generally made as advance payments. Except as indicated below, NIH grant payments are made by the Division of Payment Management (PMS), HHS, in accordance with Department of Treasury (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 only; i.e., in advance of no more than 3 days' need.

All Federal funds deposited in a grantee's bank account from PMS 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 (see below) 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.

Payments under grants to foreign or international organizations, awards to individuals, and awards to agencies of the Federal Government are made by the Office of Financial Management (OFM), NIH (see Part IV).

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 access to a computer terminal or other equipment able to communicate 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 (Richmond, Virginia) ACH process.

Monthly Cash Request

Grantees not eligible for an unrestricted advance of funds by SMARTLINK II/ACH or CASHLINE/ACH are financed on a monthly cash request basis. The monthly cash request may be on either an advance or reimbursement basis, as specified by the NIH awarding office. Monthly cash requests are used where closer monitoring of grantees' cash management is required, including 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 may also be converted from an unrestricted advance payment method to monthly cash request if, during postaward administration, the GMO determines that a grantee is not com-

plying 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 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 monthly or 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.

Operational guidance for recipients is contained in the *DHHS Manual for Recipients Financed Under the Payment Management System*. Requests for this manual and inquiries regarding payments should be directed to:

Division of Payment Management
Program Support Center
P. O. Box 6021
Rockville, MD 20852
Telephone: (301) 443-1660

Interest Earned on Advances of Grant Funds

Except as provided in 45 CFR 74.22(k), any grantee included within the applicability of those regulations (45 CFR 74.1) 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) at the address indicated above. 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 or Indian tribal governments on Federal advances of grant funds must be remitted promptly, and at least quarterly, to PMS at the address indicated above.

- **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 requested budget is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of funding, 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 in order 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 postaward changes require NIH prior approval. Prior approval requirements and authorities are discussed in "Administrative Requirements—Changes in Project and Budget."

During postaward administration, the grantee and the GMO monitor 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 may also 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 (indirect) 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

Most NIH grant awards provide for cost reimbursement (as contrasted with fixed-price arrangements) and are subject to government-wide or HHS-wide cost principles. The cost principles establish standards for allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or F&A costs, and set forth allowability 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. These cost principles are not applicable to NIH fellowship awards. The allowable use of funds under NIH fellowships is included in "National Research Service Awards" in Part III.

- 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[3]
- 45 CFR Part 74, Appendix E—Cost Principles for Hospitals
- 48 CFR Subpart 31.2 (*Federal Acquisition Regulation*)—Cost Principles for Commercial Organizations

[3]A few of the 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.

Grantees are able to use their own previously developed 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.

The cost principles address four tests—reasonableness (including necessity), allocability, consistency, and conformance with limitations or exclusions as specified in the terms and conditions of the award, including those in the cost principles themselves—that NIH follows in determining the allowability of costs. These 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 cost requested in a budget is awarded, as requested, does not ensure a determination of allowability. The organization is responsible for presenting costs consistently and must not include costs associated with their F&A rate as direct costs.**

The cost principle tests are highlighted here to indicate their importance to the judgments NIH and other Federal staff will make before, during, and after performance concerning the costs that NIH will fund, and to indicate the variety of factors that will be taken into account in determining the allowability of costs.

Reasonableness

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 at the time 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 institutional policies in incurring the cost; 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, etc., 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

The fourth aspect of allowability—conformance with limitations and exclusions as contained in the terms and conditions of award—varies by the type of activity, the type of recipient, and other variables of individual awards. The section titled "Allowability of Costs/Activities" provides information common to most NIH grants and, where appropriate, specifies some of the applicable distinctions if there is a different treatment based on the type of grant or grantee. Part III contains additional information on allowability of costs for particular types of grants/grantees/activities.

Direct Costs and Facilities and Administrative (Indirect) Costs[4]

Project costs consist of the allowable direct costs incident to the performance of the grant activities 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 are usually treated as F&A 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. 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.

Except as provided below, NIH will not reimburse F&A costs unless the grantee has established an F&A (indirect cost) rate covering the applicable activities and period of time. These rates are negotiated on behalf of NIH by the Division of Cost Allocation (DCA), HHS, the Office of Contracts Management (OCM), NIH (responsible for negotiating F&A 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.

F&A cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant agency, and must conform to other cost policies in this policy statement. The following informational brochures,[5] which may be obtained from DCA, provide guidance on preparing F&A cost[6] proposals.

- *A Guide for Colleges and Universities* (OASC-1, Revised)
- *A Guide for Hospitals* (OASC-3, Revised)
- *A Guide for Non-profit Institutions* (OASC-5, Revised)
- *A Guide for State, Local, and Indian Tribal Governments* (ASMB C-10)

Further information concerning the establishment of F&A rates and the reimbursement of F&A costs may be obtained from DCA or OCM (see Part IV). DCA should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of OMB Circular A-21.

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[4] The term "facilities and administrative costs" is not yet used universally in the cost principles and other documents cited in this section. This term and the term "indirect costs" may be used interchangeably to determine applicable policies. For NIH purposes, these costs will be referred to as "facilities and administrative," or "F&A," costs; however, other documents or non-NIH functions may refer to them as "indirect costs."

[5] These brochures are in the process of being updated. *The Guide for State, Local, and Indian Tribal Governments* was updated and reissued in April 1997, superseding *A Guide for State and Local Government Agencies* (OASC-10); the other guides, although dated and not entirely consistent with recent changes to the cost principles, may still be used as guidance.

[6] These brochures use the term "indirect costs."

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. Those grantees subject to OMB Circular A-21 may not rebudget from direct costs to accommodate a rate increase unless the rate in effect at the time of award was provisional. However, NIH will not generally award additional F&A costs beyond those calculated in the approved budget.

For grantees other than those subject to OMB Circular A-21, F&A costs awarded may be subject to upward or downward adjustment, depending on the type of rate negotiated, and these 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.

For all grantees, F&A costs are subject to downward adjustment if the proposal that served as the basis for the negotiation included unallowable costs.

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 government 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(s) than the rate(s) used in the grant award is negotiated and the resulting rate agreement becomes effective more than 1 calendar month before 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.

Grantees that use microcomputer-based automatic data processing systems to prepare F&A cost proposals, supporting schedules, etc. must be prepared to loan to HHS copies of the electronic media on which the proposal data are stored (e.g., computer disks) in addition to the operating application software and associated user documentation for analyzing and manipulating the data. Materials on loan to HHS will be used solely for review and analysis of the proposal and will be returned to the grantee after the rates are negotiated. When grantees obtain proprietary software packages designed or intended to be used for preparing F&A cost proposals, they must make sure that the terms of the acquisition (or other arrangement with the software vendor) permit loaning the software to HHS.

F&A costs are not provided if the type of award does not allow reimbursement of such costs. This includes the following classes of awards:

- **Fellowships:** F&A costs will not be provided on fellowships or similar awards

where 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, grants to foreign and international organizations, and grants to Federal institutions:** F&A costs will not be provided on grants to these entities except as specified in "Grants to Foreign Institutions, International Organizations, and Domestic Grants with Substantial Foreign Components" in Part III.

- **Grants in support of scientific meetings (conference grants):** F&A costs will not be provided under grants in support of scientific meetings.

Other circumstances under which it is not necessary for a grantee to establish an F&A rate include:

- **Research training grants and career development awards:** F&A costs under research training grants and career development awards will be reimbursed at a rate of 8 percent of total allowable direct costs, exclusive of tuition and related fees, health insurance, expenditures for equipment, and contracts in excess of $25,000, regardless of actual F&A costs, unless the grantee is a State government, local government, or Indian tribal government. Such grants to these governmental organizations will be reimbursed on the basis of their negotiated F&A rates.

- **Where the organization's total operations consist of a single grant-supported project or where 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").

Cost Transfers, Overruns, and Accelerated and Delayed Expenditures

Cost transfers to NIH grants by grantees, or by consortium participants or contractors under grants, that represent corrections of clerical or bookkeeping errors must be accomplished within 90 days of when the error is 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 institutional 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 budget period 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"). Frequent errors in recording costs may indicate the need for accounting system improvements and/or enhanced internal controls. 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 may also require a grantee to take corrective action by imposing additional terms and conditions on an award(s).

The GMO monitors grantee expenditure rates within and between budget periods of individual grants. 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. Although NIH allows its grantees certain flexibilities with respect to rebudgeting, carryover balances, and preaward costs (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 and/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 and/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, if a cost benefits two or more projects or activities in proportions that can be determined without undue effort or cost, it should be allocated to the projects on the basis of the proportional benefit. If a cost benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved, it may be allocated or transferred to the benefited projects on any reasonable basis. If the grantee wants to allocate costs normally assignable to multiple projects to one of those projects or else to treat multiple projects as a single cost objective, it must obtain NIH prior approval for this "closely related work" in accordance with the following:

- The grants must have the same PI and be funded by a single IC,
- The grants must be scientifically and technically related,
- There must be no change in the scope of the individual grants involved,
- The arrangement must not be detrimental to the effort approved under each individual award, and
- The relatedness must not be used to circumvent the terms and conditions of an individual award.

Awards under the Federal Demonstration Partnership (FDP) are permitted, with funding agency approval, to use the "program of related projects" provision of the FDP terms and conditions to treat multiple projects under the same or different PIs and/or different funding agencies as a single cost objective for purposes of OMB Circular A-21.

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 and in the HHS guides available from DCA.

Applicable credits to direct charges made to NIH grants must be treated as an adjustment on the grantee's Financial Status Report (FSR), whether those credits accrue during or after the period of grant support. (See "Administrative Requirements—Monitoring—Reporting" and "Administrative Requirements—Closeout—Final Re-

ports.") The 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, institutions to facilitate the administration of research and other programs supported by Federal funds. Such legally independent institutions are often referred to as "foundations," although this term does not necessarily appear in the name of the institution. 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 a 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.
- The affiliated organizations submit joint applications for an NIH grant award, and the grant award is made to them jointly.

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. However, the services may be acceptable for cost-sharing purposes.

Allowability of Costs/Activities

The governing cost principles address selected items of cost, some of which are mentioned in this section for emphasis. The cost principles themselves should be consulted for the complete explanation of allowability or unallowability for those items or types of cost. This subsection also includes NIH-specific requirements concerning costs and activities.

This subsection is not intended to be all-inclusive. The allowability of costs under NIH grants may be subject to additional or alternative 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 IC GMO.

If a cost is allowable, it is allocable as either a direct cost or an F&A cost, depending on the grantee's accounting system. For some costs addressed in this section, the text specifies whether the cost is usually a direct cost or an F&A cost, but it does not address that aspect of allocability for every category of cost.

Unless otherwise indicated in the NGA, an award based on an application that includes specific information concerning any costs and/or activities requiring prior approval constitutes the prior approval for those costs/activities. The grantee is

not required to obtain any additional approval for those costs/activities. Postaward 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."

Contractors under grants are subject to the requirements of the cost principles otherwise applicable to their organization and to any requirements placed on the contractor by the grantee in order 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" in Part III) but NIH will not provide profit or fee under any other grant program or support mechanism to any type of recipient. A fee may not be paid by a grantee to a consortium participant, including a for-profit organization, under a consortium agreement.

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: Alteration and renovation (A&R), also termed "rearrangement and alteration," is defined as work required to change the interior arrangements or other physical characteristics of an existing facility or of installed equipment so that it may be more effectively utilized for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement.

Under NIH grants, 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 of Part III, as applicable. Individual A&R projects exceeding $500,000 will be subject to the requirements in Part III.

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 this policy. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames in order 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 pur-

pose other than human occupancy, such as storage; and

- 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 constitute a change in scope. If the rebudgeting results in an A&R project exceeding $300,000, NIH will consider the budgeting to be a change in scope and the grantee must submit to the NIH IC the documentation specified in "Construction Grants" in Part III for approval of A&R projects above that dollar level.

Animals: Allowable for the acquisition, care, and use of experimental animals. 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* (NIH Pub. No. 80-2006, October 1979), available from the National Center for Research Resources, 6705 Rockledge Drive, Bethesda, MD 20892-7965.

Audiovisual Activities: Allowable for the production of an audiovisual. "Audiovisual" means any product containing visual imagery or 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 or 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 having 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 general public audiences (i.e., persons who are not researchers or health professions personnel and/or who are not directly involved in project activities either 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"). 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 production of this 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 considered 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 includes more than one project, but the costs can be specifically identified with, and allocated to, each project on a proportionate 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 should generally be provided as part of normal library services and treated as F&A costs rather than being directly charged.

Building Acquisition: Unallowable unless building acquisition or construction is specifically authorized by program legislation and is provided for in the grant award. Those NIH programs that have such statutory construction authority are generally intended to enhance research infrastructure through the establishment of new or modified facilities; therefore, lease-versus-purchase considerations are not normally associated with these awards. (See "Rental or Lease of Facilities and Equipment" in this subsection.) 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 may also be charged to the grant. (See also "Construction Grants" in Part III.)

Child Care Costs: Allowable if incurred to assist patients to participate as subjects in research projects. Such costs may also 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, telephone surveys, telegrams, and postage, and are usually treated as F&A costs.

Conference Grant Costs: See "Support of Scientific Meetings (Conference Grants)" in Part III for NIH policies for support of 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 Part III for policies for consortium agreements.)

Construction: Allowable only when program legislation specifically authorizes new construction, modernization, or 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 Part III).

Consultant Services: Allowable. A consultant is an individual retained to provide professional advice or services for a fee but 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. 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. In order to prevent apparent or actual conflicts of interest, grantees, consortium participants, and contractors under grants must establish written guidelines indicating the conditions, if

any, under which the payment of consulting fees to employees is proper.

In unusual cases and with authorization as indicated below, consulting fees paid by an educational institution to a salaried faculty member that represent 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. In all other cases, consulting fees paid to employees of a grantee, a consortium participant, or a contractor in addition to salary may be charged to NIH grant-supported projects only when all of the following conditions exist:

- The policies of the grantee, consortium participant, or contractor permit such consulting fee payments to its own employees regardless of whether Federal grant funds are received;
- The consulting services are clearly outside the scope of the individual's salaried employment;
- It would be inappropriate or not feasible to compensate the individual for those services through payment of additional salary; and
- Approval is obtained as specified below.

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 or 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(s); 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 Part III for allowable costs associated with consultant payments to Federal employees as well as 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 (see also "Reserve Funds" in this subsection). (See "Construction Grants" in Part III concerning contingency funds under construction grants.)

Customs and Import Duties: Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (See Part III for allowability of these costs under grants to foreign institutions, international organizations, and domestic organizations performing projects with a substantial foreign component.)

Depreciation or Use Allowances: Allowable. Such costs are usually treated as F&A costs. De-

preciation 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 the Food and Drug Administration 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 institutional 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.

Conference grant funds may not be used for the purchase of 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 Part III 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 when incurred as a result of compliance with specific provisions of an award, or when such payments are authorized in advance in writing by the 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 as of the organization's fiscal year that starts after September 30, 1998. For policies applicable to tuition remission for students working on grant-supported projects, see "Salaries and Wages" in this subsection. See "National Research Service Awards" in Part III for the allowability of tuition costs for trainees and fellows.

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.

Independent Research and Development Costs: Unallowable, including their proportionate share of F&A costs.

Insurance: Allowable. Insurance is usually 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, it 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 costs of insuring equipment, whether purchased with project funds or furnished as Government-owned property, should normally be included in F&A costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy.

Medical insurance for trainees and fellows is addressed in "National Research Service Awards" in Part III.

Interest: Allowable as an F&A cost for certain assets as specified in the applicable cost principles. Unallowable for hospitals.

Leave: Allowable for employees as an employee fringe benefit (see "Fringe Benefits" in this subsection). See "National Research Service Awards" in Part III for NIH policy on leave for trainees and fellows.

Legal Services: Allowable. Generally treated as an F&A cost but may be treated as a direct cost, subject to the limitations described in the applicable cost principles, 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 awarding office 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 awarding office GMO if it intends to engage in these activities. (See also "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying" and "Administrative Requirements—Monitoring—Reporting" concerning lobbying restrictions and required certification and reporting.)

Meals: Allowable for subjects and patients under study only, 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 toys, games, etc. 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 former 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 former 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.

Preaward (Preagreement) 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 prior to the effective date of a new or competing continuation award if such costs:

- Are necessary to conduct the project, and
- Would be allowable under a potential award without prior approval.

If specific expenditures or activities would otherwise require prior approval, the grantee must obtain NIH approval prior to incurrence of the cost. NIH prior approval is required for any costs to be incurred more than 90 days prior to the beginning date of a new or competing continuation award.

Grantees may incur preaward costs prior to the beginning date of a noncompeting continuation award without regard to the time parameters stated above.

The incurrence of preaward costs in anticipation of a competing or noncompeting 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 preaward costs incurred.

NIH expects the grantee to be fully aware that preaward 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 either direct costs or F&A costs, if they benefit more than one sponsored agreement or if they benefit the grant and other work of the institution.

Publications: Allowable. Page charges for publication in professional journals may be paid from

project funds 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 are also allowable.

Publications, journal articles, etc. 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 and Intellectual Property Rights, Including Unique 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 pre-employment 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 (see also "Travel" and "Relocation Costs" in this subsection and "National Research Service Awards—Institutional NRSA (training grants)" in Part III).

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 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.

In change of grantee organization situations, 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").

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, insurance, etc. 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 cost 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), either 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 patients participating in research programs are allowable if the grantee has obtained NIH prior approval to incur patient care costs either as part of an approved grant application or through a postaward prior approval request. In addition, except for grants subject to expanded authorities (see "Administrative Requirements—Changes in Project and Budget"), NIH prior approval is always required to rebudget additional funds into or to rebudget funds out of the research patient care costs category.

"Routine services" include the regular room, dietary and nursing 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 are customarily made in addition to routine services; e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology. See "Research Patient Care Costs" in Part III 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 patients, including inpatients, outpatients, subjects, volunteers, and donors. Such costs are considered to be 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 (see also "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 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 limitation does not apply to consultant payments but does apply to consortium participants (see "Consortium Agreements" in Part III).

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.
- Time and attendance, and payroll distribution records for nonprofessional 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 periods covered by the reports. 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 nonprofessional employees, additional supporting reports, indicating the total number of hours worked each day, must be maintained in conformance with Department of Labor 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 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 that is based on budgeted, planned, or assigned work activity, and is updated to reflect any significant changes in work distribution, including incorporation into the organization's official records and identification of 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 official(s) 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 must also identify each category of activity needed to identify F&A costs and the functions to which they are allocable. For professorial and other professional staff, the activity reports will be prepared each academic term, but no less frequently than every 6 months. For other employees, unless NIH agrees to alternate arrangements, the reports will be prepared no less frequently than monthly and will coincide with one or more pay periods; or

- A multiple confirmation records system for professorial and other professional staff supported by records certifying costs separately for direct costs and F&A costs, with reports prepared each academic term, but no less often than 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.

- Charges for work performed by faculty members on NIH grants during the summer months or other periods not included in the base salary period will be determined for each faculty member at a rate not exceeding the base salary divided by the period to which the base salary relates. The base salary period used in computing charges for work performed during the summer months will be the number of months covered by the faculty member's official academic year appointment.

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 authorized institutional official no less frequently than every pay period.

Overtime Premiums: Premiums for overtime are generally allowable (see the applicable cost principles); however, such payments are not allowable for faculty members at institutions of higher education. Where 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.

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) performing necessary work are allowable, provided:

- There is a bona fide employer-employee relationship between the student and the organization for the work performed;
- The tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work; and
- It is the organization's practice to compensate students similarly in non-sponsored as well as sponsored activities. However, compensation may not be paid from an NIH research grant that supports the same research that is part of the trainee's/fellow's approved training experience.

NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of its current operating guidelines. 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 and should be treated as direct or F&A costs according to the actual work being performed. Tuition remission may be charged on an average rate basis.

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 institutional services and central facilities owned by the recipient 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, employer-employee agreement, established policy constituting in effect an implied agreement on the part of the organization, or 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 NIH training grants and fellowships. 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 "National Research Service Awards" in Part III. 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. See "Con-

struction Grants" in Part III for allowability of taxes in projects involving construction.

Termination or Suspension Costs: Unallowable except as provided below. If a grant is terminated or suspended, the grantee shall not incur new obligations after the effective date of the termination or suspension and shall 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 prior to 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 as follows. 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 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 prior approval is obtained, as appropriate.

A trailer or modular unit properly classified as real property or as equipment at the time of acquisition shall retain 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 "National Research Service Awards" in Part III 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. Consistent with the organization's established travel policy, such 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 U.S. and its posses-

sions and territories and also travel between the U.S. and Canada and within Canada.

Foreign travel is defined as any travel outside of Canada and the U.S. and its territories and possessions. However, for an organization located outside Canada and the U.S. and its territories and possessions, foreign travel means travel outside that country.

In all cases, travel costs are limited to travel allowed by formal organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. Grantees are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets where travel schedules can be planned in advance (such as for national meetings and other scheduled events). If the recipient organization has no formal travel policy, the Federal Travel Regulations issued by the U.S. General Services Administration, including maximum per diem and subsistence rates prescribed in those regulations, shall be used to determine the amount that may be charged for travel costs. For-profit grantees' allowable travel costs may not exceed those established by the Federal Travel Regulations. This information is available at **http://www.gsa.gov**.

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 U.S. and a foreign country or between foreign countries. This requirement shall not be influenced by factors of cost, convenience, or personal travel preference.

Patient Travel: If research patient care is an approved activity of the grant-supported project, the costs of transporting patients to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose may be allowable. (See "Research Patient Care Costs" in Part III.)

Applicants and grantees should consult application instructions to determine how to budget for "travel" costs under specific mechanisms and for certain types of travelers since they are not all required to be budgeted as "travel."

Changes in Project and Budget

NIH grantees are, in general, allowed a certain degree of latitude to rebudget within and between direct cost budget categories to meet unanticipated needs and to make other types of postaward changes. Some changes may be made by the grantee only within limits established by NIH. Other changes require NIH prior written approval before modifying the budget or undertaking the activity in question. The degree of discretion permitted varies by type of grant, grantee, and coverage by, or participation in, a special initiative. The changes that may be made under the grantee's authority and the changes that require NIH approval are outlined below and in Part III. In addition, individual awards may restrict grantees' authorities to make budget and project changes without NIH prior approval. This section deals only with grantee-initiated changes. Changes in project or budget resulting from NIH-initiated actions are discussed in later sections of this Part.

If NIH approval is required, it must be requested of, and obtained from, the NIH awarding office GMO in advance of the change or obligation of funds as specified below under "Requests for Approval."

Prior Approval Requirements

The following listing of prior approval requirements applies in its entirety to NIH grants other than those operating under expanded authorities and construction grants. If an approval requirement does not apply under expanded authorities, it is noted in this list. Part III should be reviewed for other prior approval requirements unique to a type of grant, such as construction grants, or type of recipient, such as for-profit organizations. Additional prior approval requirements may be imposed by specific terms of the NGA, program legislation, regulations, or policies. Therefore, the following list may not be all-inclusive; however, it is NIH's implementation of 45 CFR 74.25, Revision of budget and program plans, and 45 CFR 92.30, Changes. If a prior approval category specified in those regulations is not included in this list, NIH has waived the requirement, as permitted by those regulations.

For those categories or types of actions listed below, prior approval is required whether or not the change has a budgetary impact.

Change in Scope, including Significant Rebudgeting: 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 NIH for changes in scope, direction, type of 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 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.
- Shifting the research emphasis from one disease area to another.
- Applying a new technology; i.e., changing assays from those approved to a different type of assay.
- Transferring the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. **NOTE: This type of action always requires NIH prior approval for grants not**

subject to expanded authorities (see "Expanded Authorities" below).

Once approval is obtained, transferring the same work to a different third party does not require NIH approval.

- Change in key personnel whose expertise is critical to the approved project.

- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval under rules governing budget changes. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established at the time of the competing award by more than 25 percent of the total costs awarded. For example, if the award budget for total costs is $200,000, NIH prior approval is required for any rebudgeting that would result in an increase or decrease of more than $50,000 in a budget category. The baseline used for determining significant rebudgeting excludes the effects of prior year carryover balances but includes competing and noncompeting supplements. When the applicable threshold is reached, the grantee must consult with the GMO for a decision as to whether the rebudgeting constitutes a change of scope. If the GMO determines that the significant rebudgeting constitutes a change of scope, NIH prior approval is required.

- Incurrence of patient care costs if not previously approved by NIH or if a grantee desires to rebudget additional funds into or rebudget funds out of the patient care category. **NOTE: These types of actions always require NIH prior approval for grants not subject to expanded authorities** (see "Expanded Authorities" below).

Preaward Costs: See "Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Preaward (Preagreement) Costs."

Change in Status, Including Absence, of Principal Investigator and Other Key Personnel: The grantee is required to notify NIH if the PI or other key personnel 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 his or her time devoted to the project by 25 or more percent 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, including any replacement PI or other key personnel proposed by the grantee.

The request for approval of a substitute PI/key person should include a justification for the change, the curriculum vitae 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 NIH, the grant may be suspended and/or terminated. If the grantee wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the awarding office GMO, in writing, of its wish to terminate, and NIH will forward closeout instructions.

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 date of the approved project period. Such a change of grantee organization may be accomplished under most NIH grants, including construction grants, if:

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

- A noncompeting 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"); or

- 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 domestic organization to another domestic organization or from a foreign organization to a domestic 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 organization may not take place where it will involve the transfer of a grant to or between foreign institutions or international organizations. In addition, a grant to an individual may not be transferred. However, an individual fellowship may be transferred to a new organization and this would be considered 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 request for a change of grantee organization must include submission of a Relinquishing Statement and a Final Invention Statement and Certification from the original grantee as well as submission of an application (PHS-398) from the proposed grantee. The application from the proposed grantee should include, at a minimum:

- A face page;
- Budget pages (current and future years);
- An updated biographical sketch;
- A statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, providing updated information;
- An updated "other support" page(s), if necessary;
- A resources page;
- A checklist page;
- An approved IRB/IACUC assurance, if applicable; and
- If the change includes the transfer of equipment purchased with grant funds, the application must include a detailed list. This list, as part of a transfer application, serves as an acceptance of title by the new organization.

NIH may request additional information necessary to accomplish its review of the request.

A change of grantee organization request must be made prior to 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 will normally 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 competitive 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 administra-

tive requirements are not met, the NIH awarding office may require a competitive review or may disapprove the request and, if appropriate, terminate the award.

As stated above, the original grantee must provide a written statement relinquishing its interests and rights to the grant in accordance with instructions from the NIH awarding office. 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, which will reflect 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 direct cost level (plus applicable F&A costs) previously committed.

Change in Grantee Organizational Status: Grantees must notify NIH, in advance, of certain changes in organizational status. This notification is required to ensure that the grantee is still able to meet its legal and administrative obligations to NIH and that payments are not interrupted.

The following organizational changes must be reported to NIH prior to the change:

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

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

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

Neither a name change nor a successor-in-interest is considered a "change of grantee organization" (as described above).

Grantees are encouraged to contact the GMO of the lead IC to explain the nature of the change and receive guidance on whether it will be treated as a name change or successor-in-interest. The lead IC will ordinarily 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 successor-in-interest or name change should be submitted to NIH as soon as possible so that NIH can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For a successor-in-interest, a letter signed by the appropriate institutional officials of the current grantee (transferor) and the successor-in-interest (transferee) must be sent to the affected NIH ICs, following consultation with the GMO of the lead IC. The letter must:

- Stipulate that the transfer was 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 records to reflect the transferee as the grantee of record, and
- State the effective date of the transfer.

The letter should be accompanied by: a list of the grants to be transferred; a revised completed grant application face page for the affected grant(s) showing the transferee as the applicant organization, along with information regarding changes in taxpayer identification or entity identification numbers, F&A costs (including a copy of the rate agreement), and the use of human subjects or animals. Upon receipt 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 IC must include the effective date of the change. Revised face pages are not required for name changes since name changes are processed with the next award action and a face page will be received from the organization as part of that action.

Addition of a Foreign Component: Addition of a substantial foreign component under a grant to a domestic organization.

Award Terms and Conditions: Deviations from special terms or conditions stated in the NGA or from the terms and conditions included in this policy statement.

Restrictions on Notice of Grant Award: Undertaking any activities disapproved or restricted as a condition of the award.

Carryover of Unobligated Funds from One Budget Period to Another Within an Approved Project Period: NOTE: This action is generally allowable without prior approval under expanded authorities unless restricted (see "Expanded Authorities" below).

Extension of a Project Period With or Without Additional Funds: A request for a noncompeting extension of a project period should be submitted to the IC GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests are usually for a period 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, and may be made without funds or with a minimal amount of additional funds. The request must specify the proposed revised ending date and must include justification for both the extension and any additional funds requested. Special justification will be required for an additional extension that would exceed an initial 12-month extension. NIH will not approve such requests if the primary purpose of the proposed extension is to permit the use of unobligated balances of funds. **NOTE: These requirements do not generally apply under expanded authorities with respect to a "no-cost" extension of the final budget period of a project period** (see "Expanded Authorities" below).

Equipment Purchase: Equipment exceeding $25,000 per unit, regardless of the amount of NIH funding to be used. **NOTE: This requirement is not generally applicable under expanded authorities unless the purchase may result in a change in scope** (see "Expanded Authorities" below).

Retention of Research Grant Funds When an Independent Scientist Award is Made: Funds budgeted under an NIH grant for an individual's salary and/or fringe benefits, but available as a result of receiving an Independent Scientist Award (ISA) for that individual, may not be used for any other purpose without NIH prior approval.

Alterations and Renovations: NIH prior approval is required for an A&R project exceeding $300,000 (see "Construction Grants" in Part III for documentation requirements).

Transferring Amounts from Trainee Costs: The transfer of amounts previously awarded for trainee costs (stipends, tuition, and fees) to other categories of expense. This excludes trainee travel, which NIH does not consider to be a trainee cost, and training-related expenses (see "National Research Service Awards" in Part III).

Capital Expenditures: Capital expenditures for land or buildings. Also, 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.

Need for Additional NIH Funds: 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, noncompeting continuation, or competing continuation application was submitted, is a noncompeting supplemental application. Such requests are submitted directly to the GMO, in writing, and are not required to compete with other applications for funding.

Closely Related Work: When salaries or other costs are being supported by two or more scientifically and technically related NIH grant projects with the same PI and funded by the same IC, grantees may charge those costs to any one of those projects or treat multiple projects as a single cost objective only with NIH prior approval. NIH will not approve such requests if there is a change in the scope of the individual grants involved, relating the costs will be detrimental to the conduct of work approved under each individual award, or the projects are being related to circumvent the terms and conditions of an individual award. (See "Cost Considerations—Allocation of Costs and Closely Related Work.")

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

Program Income: The use of any alternative for disposition of program income other than that specified in the terms and conditions of award must have NIH prior approval (see "Administrative Requirements—Management Systems and Procedures—Program Income").

Expanded Authorities

NIH has waived the requirement for its approval of specified actions under certain awards and has provided the authorities (hereafter "expanded authorities") to grantees to take such actions without NIH prior approval. This subsection describes the authorities unique to grants subject to expanded authorities. In using these expanded authorities, grantees must ensure that they exercise proper stewardship over Federal funds and that costs charged to the awards are allowable, allocable, reasonable, and consistently applied regardless of the source of funds. Expanded authorities apply to the following mechanisms:

- "R" series (Research Project Grants), except R41, Phase I Small Business Technology Transfer (STTR) Grants, and R43, Phase I Small Business Innovation Research (SBIR) Grants
- Program Project Grants (P01)
- "K" series (Career Development Awards)
- Minority High School Student Research Apprentice Program Awards (S03).

NIH ICs may also authorize some or all of the expanded authorities for additional awards or classes of awards.

Expanded authorities are not provided under awards to individuals. Certain support mechanisms or grantees may also be excluded from

expanded authorities. If excluded, the NGA will indicate this change from the standard terms and conditions. This may include grants or grantees that require closer project monitoring or technical assistance, such as clinical trials and certain large multi-project grants. Therefore, grantees must review the NGA to determine whether they are permitted to use expanded authorities.

When a grant is under expanded authorities, the grantee may take the following actions without NIH prior approval unless one or more of these authorities is overridden by a special term or condition of the award. Several of the 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 shall be grounds for excluding that grantee from these special authorities. Even where the grantee is authorized to use expanded authorities, if it is determined, through audit or otherwise, that costs do not meet the tests of allowability, allocability, reasonableness, and consistency, the costs may be disallowed.

Extension of a Project Period Without Additional Funds: The grantee may extend the final budget period of the 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 awarding office, there will be no change in the project's originally approved scope or objectives, 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 phaseout 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 prior to 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 grant through this process, the grantee agrees to update all required certifications, including 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" above for extensions requiring additional funds.)

Carryover of Unobligated Balances: Except for funds restricted in an NGA, grantees are authorized to carry over unobligated funds remaining at the end of a budget period. For awards under the Streamlined Noncompeting Award Process (SNAP), funds are automatically carried over and are available for expenditure during the entire project period. However, under those awards, the grantee will be required to indicate, as part of its noncompeting continuation request, whether its estimated unobligated balance (including prior year carryover) is expected to be greater than 25 percent of the current year's total budget. If so, the grantee must provide an explanation and indicate plans for expenditure of those funds if carried forward. (See "Administrative Requirements—Noncompeting Continuation Awards.")

For those awards subject to expanded authorities but excluded from SNAP; e.g., P01s and R35s, 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 awarding office GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project,

and may request additional information from the grantee, including a revised budget, as part of the review. If the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may take one, or a combination, of the following actions: restrict the grantee's authority to automatically carry over unobligated balances in the future or use the balance to reduce or offset NIH funding for a subsequent budget period. Any amount not identified for carryover may be used as an offset. A revised NGA will not be issued to reflect the carryover.

Use of Program Income: The additive costs alternative for the use of program income will apply to awards subject to expanded authorities unless program regulations or the NGA specify another alternative or a combination of alternatives or the grantee is a for-profit organization other than an SBIR/STTR awardee (see "Administrative Requirements—Management Systems and Procedures—Program Income").

Requests for Approval

All requests for NIH awarding office prior approval must be made, in writing, to the awarding office GMO no later than 30 days before the proposed change. The request must be signed by both the PI and the authorized institutional official. Failure to obtain prior approval, when required, from the appropriate NIH awarding office may result in the disallowance of costs, termination of an award, or other enforcement action within NIH's authority.

The GMO will review the request and inform the authorized institutional official, in writing, of the final disposition of the request. Only responses signed 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 postaward 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, the prior approval authority is usually the grantee. However, the grantee may not approve any action or cost that is inconsistent with the purpose or terms 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 shall obtain that approval from NIH before giving its approval to the consortium participant.

Noncompeting Continuation Awards

The "Application for Continuation of a Grant" (PHS-2590) or equivalent documentation must be submitted to, and be approved by, NIH to noncompetitively fund each additional budget period within a previously approved project period. Except for awards subject to SNAP (see below), the application includes an updated budget, progress report, and other required information.

Noncompeting continuation applications must be submitted directly to the IC GMO 2 months before the beginning date of the next budget period, unless instructed otherwise. (OPERA will provide the grantee with a computer-generated face page and necessary mailing labels approximately 4 months before the end of the current budget period.) Late submission or receipt of an incomplete noncompeting continuation application will result in delaying the issuance and funding of the noncompeting continuation award and may result in a reduced award amount.

Streamlined Noncompeting Award Process

NIH grantees (including those participating in the Federal Demonstration Partnership) are expected to follow the streamlined noncompeting process (SNAP) for mechanisms routinely covered under expanded authorities except Program Project Grants (P01s) and Outstanding Investigator Grants (R35s). NIH routinely applies expanded authorities to Program Project Grants (P01s),

Minority High School Research Apprentice Program Awards (S03s), Research Career Awards (K series), and all Research Project Grants (R series) except Phase I SBIR (R43) and STTR (R41) awards.

Any additional activity that has been included under expanded authorities at the discretion of an IC (e.g., centers, training grants, or cooperative agreements) will be excluded under SNAP unless inclusion is specifically footnoted as a term or condition of the award.

Any award excluded from expanded authorities is routinely excluded from SNAP unless specifically included in SNAP as a term or condition of the award. Individual awards may be excluded from routine inclusion under SNAP (and expanded authorities) on the basis of the following criteria:

- Grants that require close project monitoring or technical assistance; e.g., clinical trails, exceptional (high-risk) grantees, certain large individual or multiproject grants, or grants with significant unobligated balances.

- Grantees that have 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. This eliminates the need for annual budget submissions and negotiations and reduces the information NIH requires to review and approve noncompeting continuation applications and to monitor these awards. As a result, for awards under SNAP, grantees are required to submit only limited portions of the PHS-2590, including an annual progress report. Grantees are also required to submit a quarterly Federal Cash Transactions Report (FCTR) (SF-272) to PMS.

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 change(s), including termination of a previously active grant or activation of a previously pending grant, must be explained. If not, the grantee must so state.

- Will there be, in the next budget period, significant rebudgeting of funds from what was approved for the project? If so, the grantee must explain; if not, the grantee must so state. "Significant rebudgeting" occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established at the time of the competing award by more than 25 percent of the total amount awarded. The basis for determining significant rebudgeting in relation to SNAP excludes the effects of prior year carryover balances but includes competing and noncompeting supplements.

- Will there be, in the next budget period, a 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 IC 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 in order to

evaluate the project for continued funding. Failure to provide this information will result in a delayed award.

For awards under SNAP, an FSR (SF-269) is required only at the end of a competitive segment rather than annually. This 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").

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

It is NIH policy to make available to the public the results and accomplishments of the activities that it funds. Therefore, 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. This policy notwithstanding, NIH recognizes that certain research findings may result in inventions. Grantees have the prerogative to protect these inventions, as long as they abide by the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR 401. In general terms, these regulations require the grantee to utilize patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, technology transfer may take place in the form of journal articles or other publications or through the availability of research products or resources.

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

Rights in Data (Publication and Copyrighting)

In general, grantees own the data generated by or resulting from a grant-supported project. Special terms and conditions of the award may specify alternative rights; e.g., under a cooperative agreement or if there are shared rights to data. Except as otherwise provided in the terms and conditions of the award, the grantee is free to copyright without NIH approval when publications, data[7], or other copyrightable works are developed under, or in the course of, work under an NIH grant. Copyrighted or copyrightable works also include materials developed by students, fellows, or trainees under awards whose primary purpose is to further the education or training of such individuals. Whenever any work subject to this copyright policy is developed by a consortium participant or a contractor (or subcontractor) under a grant, the written agreement/contract must require the consortium participant/contractor (subcontractor) to comply with these requirements and can in no way diminish NIH's rights in that work. NIH must be provided a royalty-free, nonexclusive, and irrevocable license for the Government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes.

Grantees may arrange for publication of initial reports of original research, supported in whole or in part by NIH grant funds, in primary scientific journals and for copyright by the journal unless the journal's copyright policy would preclude individuals from making or having made, by any means available to them without regard to the copyright of the journal and without royalty, a single copy of any such article for their own use (see 45 CFR 74.36 and 92.34). The disposition of royalties and other income earned from a

[7] 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.

copyrighted work is addressed in "Administrative Requirements—Management Systems and Procedures—Program Income." Grantees are encouraged to assert copyright in scientific and technical articles based on data produced under the grant where this is necessary to effect publication in academic, technical, or professional journals, symposia, proceedings, or similar works.

Grantees are required to place an acknowledgment of NIH grant support and a disclaimer, as appropriate, on any publication written or published with such support and, if feasible, on any publication reporting the results of, or describing, a grant-supported activity. An acknowledgment shall be to the effect that:

"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."

In the event that the recipient wishes to join with NIH in a simultaneous news release announcing the results of a project, the action should be coordinated with the awarding office.

One copy of each publication resulting from work performed under an NIH grant-supported project must accompany the annual progress report submitted to the NIH awarding office (see "Administrative Requirements—Noncompeting Continuation Awards").

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 and/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.

Restricted availability of unique resources upon which further studies are dependent can impede the advancement of research and the delivery of medical care. 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. This policy applies to grants, cooperative agreements, and contracts.

Investigators who believe they will be unable to implement this policy should promptly contact the appropriate Program Official to discuss the circumstances, obtain information that might facilitate compliance with this policy, and reach an understanding in advance of the subsequent award. In order 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. In the case of unique biological information, such as DNA sequences or crystallographic coordinates, investigators are expected to submit them to the appropriate data banks, because, otherwise, they are not truly accessible to the 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.

Inventions and Patents

Pursuant to the Bayh-Dole Act and Executive Order 12591 (April 10, 1987), all recipients of NIH research funding (i.e., all NIH grantees and contractors and consortium participants and other organizations receiving funds under NIH grants and contracts, whether small businesses, large businesses, or non-profit organizations) are subject to the same invention reporting requirements and regulations. These are included in the regulations issued by the Department of Commerce, found at 37 CFR Part 401.

Grantees (and, in some cases, employee inventors) have rights to inventions ("subject inventions") conceived or first actually reduced to practice in the performance of work under an NIH award. Grantee organizations must fulfill the following requirements:

- Establish and implement an employee invention reporting policy (37 CFR 401.14(f)(2));
- Report all subject inventions within 2 months to OPERA (37 CFR 401.14(c) and (l));
- Elect title (or waive title) within 2 years of reporting to OPERA (37 CFR 401.14(c)(2) and (l));
- File for patent within 1 year of electing title or public disclosure, whichever comes first (37 CFR 401.14(c)(3));
- Upon election of title, provide a confirmatory license to the Government (37 CFR 401.14(b));
- Acknowledge NIH support in any patent application or patent (37 CFR 401.14(f)(4));
- Notify OPERA of any decision not to pursue patent rights (or licensing) (37 CFR 401.14(f)(3) and (l));
- Submit an annual utilization report for all inventions where election of title is made and for unpatented, yet licensed, inventions (37 CFR 401.14(h));
- Exercise preference for U.S. industry and, if the grantee is a non-profit organization, preference for small businesses (37 CFR 401.14(i));
- Provide one copy of each publication resulting from work performed under an NIH grant-supported project to the NIH awarding office with the annual progress report; and
- Submit a final invention statement and certification to the NIH awarding office within 90 days of the end of the project period. (37 CFR 401.14(f)(5)).

Failure of the grantee to comply with these provisions may result in the loss of patent rights. If the grantee waives its rights to the employee-inventor, these requirements apply to the employee-inventor.

As specified in 45 CFR Part 74 and 37 CFR 401.1(b), fellowships, scholarships, and training grants, which are funded by NIH primarily for educational purposes, are not subject to invention reporting requirements. The Federal Government (NIH) has no rights to any inventions, or any income resulting from inventions conceived or first actually reduced to practice during the course of such educational activities.

Invention reporting requirements and the use of the Extramural Invention Information Management System (Edison) are discussed under "Administrative Requirements—Monitoring—Reporting."

To provide a more complete description of the invention and patent reporting requirements, the complete text of the standard patent rights clauses (37 CFR 401.14) is included below and may also be found on the NIH link to the Interagency Edison Web site (**www.iedison.gov**).

Sec. 401.14, Standard Patent Rights Clauses (Small Business Firms and Non-profit Organizations) (July 1997) (NOTE: While the title of these clauses refers to small businesses and non-profit organizations, the provisions also apply to large for-profit businesses. The term "contractor" in the text applies equally to grantees.)

401.14(a) Definitions.

(1) *Invention* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(2) *Subject invention* means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) may also occur during the period of contract performance.

(3) *Practical Application* means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(4) *Made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) *Small Business Firm* means a small business concern as defined at section 2 of Pub. L. 85-536 (16 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) *Non-profit Organization* means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any non-profit scientific or educational organization qualified under a state non-profit organization statute.

401.14(b) Allocation of Principal Rights.

The contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

401.14(c) Invention Disclosure, Election of Title and Filing of Patent Application by Contractor.

(1) The contractor will disclose each subject invention to the Federal agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of

the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

(2) The contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The contractor will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the agency, be granted.

401.14(d) Conditions When the Government May Obtain Title.

The contractor will convey to the Federal agency, upon written request, title to any subject invention—

(1) If the contractor fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.

(2) In those countries in which the contractor fails to file patent applications within the times specified in (c) above; provided, however, that if the contractor has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the Federal agency, the contractor shall continue to retain title in that country.

(3) In any country in which the contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

401.14(e) Minimum Rights to Contractor and Protection of the Contractor Right to File.

(1) The contractor will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the contractor fails to disclose the invention within the times specified in (c), above. The contractor's license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the contractor is a party and includes the right to grant sublicenses of the same scope to the extent the contractor was legally obligated to do so at the time the contract was awarded. The license is transferable only with the approval of the Federal agency except when transferred to the successor of

that party of the contractor's business to which the invention pertains.

(2) The contractor's domestic license may be revoked or modified by the funding Federal agency to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR part 404 and agency licensing regulations, if any. This license will not be revoked in that field of use or the geographical areas in which the contractor has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the funding Federal agency to the extent the contractor, its licensees, or the domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the funding Federal agency will furnish the contractor a written notice of its intention to revoke or modify the license, and the contractor will be allowed thirty days (or such other time as may be authorized by the funding Federal agency for good cause shown by the contractor) after the notice to show cause why the license should not be revoked or modified. The contractor has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and agency regulations, if any, concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of the license.

401.14(f) Contractor Action to Protect the Government's Interest.

(1) The contractor agrees to execute or to have executed and promptly deliver to the Federal agency all instruments necessary to:

(i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title, and

(ii) convey title to the Federal agency when requested under paragraph (d) above and to enable the Government to obtain patent protection throughout the world in that subject invention.

(2) The contractor agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1), above. The contractor shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The contractor will notify the Federal agency of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with Government support under (identify the contract) awarded by (identify the Federal agency). The Government has certain rights in the invention."

(5) The contractor agrees to provide a final invention statement and certification prior to close-out listing all subject inventions or stating that there were none.

(6) The contractor will provide the patent application filing date, serial number and title; copy of the page of the patent application with the statement identified in (4) above (and, upon request, a copy of the patent application); and patent number and is due date for any subject invention in any country in which the contractor has applied for patent.

401.14(g) Subcontracts.

(1) The contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental or research work to be performed by a small business firm or domestic non-profit organization. The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) The contractor will include in all other subcontracts, regardless of tier, for experimental developmental or research work the patent rights clause required by (cite section of agency implementing regulations or FAR).

(3) In the case of subcontracts, at any tier, when the prime award with the Federal agency was a contract (but not a grant or cooperative agreement), the agency, subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with any proceedings under paragraph (j) of this clause.

401.14(h) Reporting on Utilization of Subject Inventions.

The contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. The contractor also agrees to provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the agency agrees it will not disclose such information to persons outside the Government without permission of the contractor.

401.14(i) Preference for United States Industry.

Notwithstanding any other provision of this clause, the contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the

United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency upon a showing by the contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

401.14(j) March-in Rights.

The contractor agrees that with respect to any subject invention in which it has acquired title, the Federal agency has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such a request the Federal agency has the right to grant such a license itself if the Federal agency determines that:

(1) Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee or licensees; or

(4) Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

401.14(k) Special Provisions for Contracts with Non-profit Organizations.

If the contractor is a non-profit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the contractor;

(2) The contractor will share royalties collected on a subject invention with the inventor, including Federal employee coinventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject invention that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application

as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the contractor could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).

401.14(l) Communication.

All NIH-related disclosures, elections, confirmatory licenses to the Government, face page of a patent application, waivers and other routine communications should be sent to the following address:

Inventions and Extramural
Reporting Branch
Division of Grants Policy,
OPERA/OER/NIH
Rockledge II, Room 3190,
MSC 7750
Bethesda, MD 20892-7750
(301) 435-1986
FAX: (301) 480-0272

For other awarding agencies, please follow their instructions. In most cases, invention information and communications should be sent to the cognizant GMO.

The NIH link to the electronic Interagency Edison extramural invention reporting system can be accessed through the Web (**www.iedison.gov**). This electronic reporting system was designed to facilitate reporting compliance and timeliness, and to reduce paperwork. Edison also has an e-mail address (Edison@od.nih.gov).

(End of clause)

In the most recent revision of 37 CFR 401, grantees are provided the option of meeting reporting requirements through electronic filing. Section 401.16, as stated below, describes changes in provisions to accommodate electronic filing.

401.16 Electronic Filing.

Unless otherwise requested or directed by the agency:

(a) The written report required in (c)(1) of the standard clause in sec. 401.14 may be electronically filed;

(b) The written election required in (c)(2) of the standard clause in sec. 401.14 may be electronically filed; and

(c) The closeout report in (f)(5) of the standard clause in sec. 401.14 and the information identified in (f)(2) and (f)(3) of sec. 401.5 may be electronically filed.

Management Systems and Procedures

Grantee institutions are expected to have systems, policies, and procedures in place by which they manage funds and activities. Grantees may use their existing systems 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 in this policy statement. NIH may review the adequacy of those systems in order to protect the Government's interests and may take appropriate action, including the use of special terms and conditions, as necessary. NIH will also oversee the performance of the grantee's systems as part of its routine postaward monitoring. The grantee's systems are also 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 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 in an appropriate manner, 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 assure that obligations and expenditures are reasonable, allocable, and allowable, and that are able to identify large unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate expenditure and obligation 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, and 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, the use or rental of real or personal property acquired under the grant, the sale of commodities or items fabricated under an award, and license fees and royalties on patents and copyrights. The requirements for accountability for these various types of income under NIH grants are specified below. 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.

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 below.

Program income, 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, earned during the period of grant support, shall be retained by the grantee and may be used in one or a combination of the following alternatives as specified by NIH. This includes income earned from charges to third parties for use of equipment or supplies acquired with NIH grant funds as well as charges for unique research resources.

- **Additive Alternative:** Added to funds committed to the project or program, and used to further eligible project or program objectives.
- **Deductive Alternative:** Deducted from total project or program allowable costs in determining the net allowable costs on

which the Federal share of costs will be based.

- **Matching Alternative:** Used to satisfy all or part of the non-Federal share of a project or program.

- **Combination Alternative:** Under the combination alternative, grantees use all program income up to (and including) $25,000 as specified for the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative.

The additive alternative will apply to program income earned under NIH awards subject to expanded authorities and to Phase I awards under the SBIR/STTR programs unless the terms and conditions of the award specify the use of another alternative(s). For all other awards, except awards to non-SBIR/STTR for-profit organizations, the combination alternative will apply unless the terms and conditions of the award indicate otherwise. The circumstances under which NIH may require use of a different alternative include when a grantee has deficient systems or where the PI has a history of frequent, large annual unobligated balances on previous grants or has requested multiple extensions of the budget/project period.

The deductive alternative will always apply to awards to non-SBIR/STTR for-profit organizations.

Sale of Real Property, Equipment, and Supplies

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

For equipment and supplies purchased under NIH grants for basic or applied research by nonprofit institutions of higher education or nonprofit 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/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 shall 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/grantees are also 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

If a grantee is accountable for the use of program income during the period of grant support (other than income resulting from royalties or licensing fees, as provided below), the amount earned and the amount expended must be reported on the FSR (SF-269). The costs associated with the generation of the "gross" amount of program income, if they are not costs 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 shall be reported on lines 10r and 10s, as appropriate, of the FSR (Long Form); program income subject to the deductive alternative shall be reported on lines 10c and 10q of the FSR (Long Form); and program income subject to the matching alternative shall be reported on lines 10g and 10q of the FSR (Long Form). (See "Administrative Requirements—Monitoring—Reporting.") For awards under SNAP, the amount of program in-

come earned shall be reported in the noncompeting continuation request and the amount expended reported on line 11g of the FCTR (SF-272). The FSR for the competitive segment must include the aggregate amounts earned and spent.

Income earned from the sale of equipment shall be reported on the FSR for the period in which the proceeds are received and in accordance with the reporting requirements for the program income alternative specified. Amounts due NIH for unused supplies shall be reflected as a credit to the grant on line 10c of the FSR (Long Form).

Where the terms of the NGA, including this policy statement, 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

Unless specific terms and conditions of the award provide otherwise, NIH grantees are not required to account for income earned from copyrighted material. However, grantees must account for royalties and licensing fees that result from NIH-funded inventions and patents. Income of this nature must be reported on the annual utilization report, which is required if the grantee decides to elect title to the invention or when licensing fees are generated for inventions that are not patented (i.e., some biological materials and unique research resources) (see "Administrative Requirements—Availability of Research Results: Publications and Intellectual Property Rights, Including Unique Research Resources" and "Administrative Requirements—Monitoring—Reporting"). If commercialization of an invention is an anticipated outcome of a research project, the NGA may include additional terms and conditions regarding the disposition of program income.

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[8], 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 recipient includes necessary modifications, attachments, etc., 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 requirements for accountability 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

[8] 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.

in advance of the acquisition. The grantee must also 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" in Part III for requirements that apply to the acquisition, use, and disposition of real property. Fixed equipment that is part of a construction grant is also 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 shall use, manage, and dispose of equipment acquired under a grant in accordance with State laws and procedures, and certain research grant recipients with exempt property (see below). These requirements do not apply to equipment for which only depreciation or use allowances are charged, donated equipment, or equipment acquired primarily for sale or rental rather than for use.

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, except that NIH has the right to require transfer of title to the 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 is subject to the full range of acquisition, use, management, and disposition requirements of 45 CFR 74.34 and 74.35, or 92.32 and 92.33. Property acquired or used under an NIH grant-supported project, including any federally owned property, is also subject to the requirements for internal control specified in 45 CFR 74.21 or 92.20, and, pursuant to 45 CFR 74.37, equipment (and intangible property and debt instruments) acquired with, or improved with, NIH funds shall not be encumbered without NIH approval.

The grantee's property management system for equipment must meet the requirements of 45 CFR 74.34(f) or 92.32, which include:

- The grantee keeps records that adequately identify items of equipment owned, according to the criteria specified in the regulations, or held by the grantee and state the current location of each item.
- At least once every 2 years, the grantee physically inventories the equipment to verify that the items covered by the records exist and are either usable and needed or listed as surplus.
- Control procedures and safeguards to prevent loss, damage, and theft and 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 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 shall compensate the NIH awarding office for its share as a credit to the grant.

State, local, or Indian tribal governments 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. This allows for the transfer of such property to the grantee when it is no longer needed under the contract.

The revocable license agreement between NIH and the grantee would provide for the transfer of the equipment for the period of the 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 *Federal Acquisition Regulation*).

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 shall 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" in Part III.

A contract under a grant must be a written agreement between the grantee and the third party. The contract must, as applicable, 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 re-

sponsibility for the direction of the project and accountability to the Government. The agreement shall, therefore, reserve sufficient rights and control to the grantee to enable it to fulfill its responsibilities.

In situations where a grantee enters into a service-type contract the term of which is not concurrent with the budget period of the award, the costs of the contract may be charged 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 NIH awarding office has been made aware of this situation either at the time of application or through postaward notification,
- The project has been recommended for a project period extending beyond the current year of support, and
- There is a legal commitment on the part of the grantee to continue the contract for its full term.

However, costs will be allowable only to the extent that they are for services that are provided during the period of NIH support. In order to limit liability in the event that 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 expiration 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 regulatory 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 "small purchase threshold" established by the Federal Property and Administrative Services Act, as amended, (currently $100,000) 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 small purchase threshold specifies a "brand name" product.
- A proposed award over the small purchase 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 small purchase.

When NIH prior approval is required, the grantee must make available sufficient information to enable review and approval or disapproval. This may include, at NIH discretion, pre-solicitation 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:

- Placing qualified small, minority, and women-owned business enterprises on solicitation lists.
- Ensuring that small, minority, and women-owned business enterprises are solicited whenever they are potential sources.
- Considering 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, if economically feasible, dividing larger requirements into smaller transactions for which such organizations might compete.
- Making information on contracting opportunities available and establishing delivery schedules that encourage participation by small, minority, and women-owned business enterprises.
- Using the services and assistance of the Small Business Administration and the Minority Business Development Agency of the Department of Commerce, as appropriate.
- Requiring the prime contractor, if subcontracts are to be let, 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, in order 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 resulting from property accountability, audit, and other requirements that 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, reporting to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Grantees are also 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 and Intellectual Property Rights, Including Unique Research Resources."

The GMO is the receipt point for most required reports, including noncompeting continuation requests, final progress reports, final invention statements and certifications, and lobbying disclosure statements. Reports must be submitted in an original and two copies unless the instructions for submission specify otherwise. Submission of these reports to individuals other than the GMO

may result in delays in processing or the submission being considered delinquent.

Grantees are allowed a specified period of time in which to submit required financial and progress reports (see 45 CFR 74.51 and 74.52, 92.40 and 92.41, and the discussion below). 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 (see also "Administrative Requirements—Enforcement Actions").

Progress Reports as Part of Noncompeting Continuation Requests

Progress reports are usually required annually as part of the noncompeting continuation request or competing continuation application. However, NIH may require these reports more frequently. The information to be included in the progress report as part of a noncompeting continuation request is specified in the PHS-2590 application instructions, which also include the alternate instructions for awards under SNAP (see "Administrative Requirements—Noncompeting Continuation Awards"). The requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, and nonconstruction activities will be specified by the NIH awarding office.

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 latter format is the "long form" and is required when a grantee is accountable for the use of program income). Except for those awards under SNAP and awards requiring more frequent reporting, the FSR is required on an annual basis. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the close of the budget period. The report must also 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 awards under SNAP, in lieu of the annual FSR, NIH will use the quarterly FCTR (SF 272), 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 there are possible performance or financial management problems. 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[9] to OFM, NIH, which, for this purpose, is equivalent to submission to the GMO. Prior to submitting FSRs to NIH, grantees must ensure that the information submitted is accurate, complete, and consistent with the grantee's accounting system. The signature of the authorized institutional official 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.

[9] Information about the electronic transmittal of FSRs may be obtained from OFM, NIH, at (301) 496-5287.

Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of award. (See "Administrative Requirements—Changes in Project and Budget" for NIH approval authorities for unobligated balances.)

Upon receipt of the annual FSR for awards other than those under expanded authorities, the GMO will compare the total of any unobligated balance shown and the funds awarded for the current budget 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; or
- Restrict from use some or all of the excess funds in the current budget period and take that amount into account when making a subsequent award.

There may be instances where the grantee is required 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. This includes expenditures resulting from underfunding a noncompeting continuation award due to a smaller unobligated balance than anticipated. **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.** 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

All inventions made in the course of, or under, any NIH research grant, including SBIR/STTR awards, must be promptly and fully disclosed to NIH within 2 months after the inventor provides written disclosure to the grantee's authorized official. The disclosure must be in writing, identify the applicable grant and the name of the inventor(s), and provide a complete technical description and other information as required by 37 CFR 401.14(c)(1) (see "Administrative Requirements—Availability of Research Results: Publications and Intellectual Property Rights, Including Unique Research Resources" for the full text of the clause).

In addition to immediate invention disclosure, each application for competing or noncompeting continuation support of an NIH grant-supported research project must include either a listing of all inventions conceived or reduced to practice during the preceding budget period or a certification that no inventions were made during the applicable period.

The grantee must also submit an annual utilization report when the grantee has elected title to an invention or when royalties or licensing fees are generated for inventions that are not patented. NIH has developed an optional on-line Extramural Invention Information Management System, known as "Edison," to facilitate grantee compliance with the disclosure and reporting requirements of 37 CFR 401.14(h). The Internet address for this system is **http://www.iedison.gov**. Information from these reports is not made publicly available.

Report to the Office of Research Integrity

The regulations governing misconduct in science require the grantee to submit an annual report (Form 6349) to the Office of Research Integrity (ORI) detailing aggregate information on allegations, inquiries, and investigations handled by the grantee in the previous year. ORI automatically sends this form to NIH grantees at the end of the calendar year (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Misconduct in Science").

Lobbying Disclosure

Grantees subject to the anti-lobbying requirements described in "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying" must submit the "Disclosure of Lobbying Activities" (Standard Form-LLL) for each payment or agreement to make payment from nonappropriated funds to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a "covered" Federal transaction.

Record Retention and Access

Grantees must generally retain financial and programmatic records, supporting documents, statistical records, and all other records of a grantee 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, the 3-year retention period will be calculated from the date the FSR for the entire competitive segment is submitted. Therefore, those grantees must retain the records pertinent to the entire competitive segment for 3 years from the date the FSR is submitted to NIH. See 45 CFR 74.53 and 92.42 for exceptions and qualifications to the 3-year requirement. 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 that:

- Financial operations are properly conducted.
- Financial reports are presented fairly and accurately.
- Applicable laws, regulations, and other grant terms have been complied with.
- Resources are managed and used in an economical and efficient manner.
- Desired results and objectives are being achieved in an effective manner.

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) (for types of organizations to which OMB Circular A-133 does not directly apply). In general, OMB Circular A-133 requires that a State government, local government or non-profit organization (including institutions of higher education) that spends $300,000 or more per year in Federal grants, cooperative agreements, and/or procurement contracts have an annual audit by an independent Certified Public Accountant or accounting firm or State auditor. The audit requirements for foreign grantees and for-profit grantees are addressed in Part III of this policy statement.

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, 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, and that they enter into written agreements with auditors that specify the rights and responsibilities of each party.

The OMB Circular explains in detail the scope, frequency, and other aspects of the audit. Some highlights of the Circular are as follows:

- Covered organizations spending $300,000 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 spending less than $300,000 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 is comprised of the following: financial statements and supplementary schedule of expenditures of Federal awards; independent auditor's report(s), 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; and, if applicable, a summary of prior audit findings and a corrective action plan.

- An audit made in accordance with OMB Circular A-133 is in lieu of a financial audit under 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 designated Federal clearinghouse at the following address:

  Federal Audit Clearinghouse
  Bureau of the Census
  E. 10th Street
  Jeffersonville, IN 47132

If HHS awards are included in the schedule of expenditures of Federal awards and the report contains adverse findings, the Federal clearinghouse will provide copies of the audit report to the HHS Office of the Inspector General clearinghouse, which 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 Government-initiated or recipient-initiated audits. Grantees are usually 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 (see "Administrative Requirements—Grant Appeals Procedures"). Refunds owed to the Government as a result of audit disallowances must be made in accordance with instructions issued by the Action Official or OFM, NIH.

See "Allowability of Costs/Activities—Selected Items of Cost" for the allowability of grantee audit costs.

Enforcement Actions

A grantee's failure to comply with the terms and conditions of award, including confirmed instances of scientific misconduct, may cause NIH to take one or more enforcement actions, depending on the severity and duration of the noncompliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies, and will generally afford the grantee an opportunity to correct the deficiencies prior to taking enforcement action unless public health or welfare concerns require immediate action. However, even if a grantee is taking corrective action, NIH may, at the same time, take proactive actions 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 actions designed to prevent future noncompliance, such as closer monitoring. If NIH imposes sanctions on a grantee as a result of misconduct in science or will more closely monitor an award(s) through the use of special conditions (see below), NIH will share this information with other HHS components.

Modification of the Terms of Award

During grant performance, the awarding office may impose special conditions to require correction of identified financial or administrative deficiencies. At the time the special conditions are imposed, the awarding office will notify the grantee of the nature of the conditions; the reason why they are being imposed; the nature of the 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 may also, for reasonable cause, withdraw approval of the PI or other key personnel for a project. The qualifications and competence of the PI and other key personnel were evaluated prior to award, and, if the awarding office has reasonable basis to conclude that the PI or other key personnel are no longer qualified to perform in that capacity, the awarding office may withdraw its approval of those individuals and 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 IC.

Suspension, Termination, and Withholding of Support

When a grantee has failed to materially comply with the terms and conditions of a grant, 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 92.43.

NIH will generally suspend (rather than immediately terminate) a grant and allow the grantee an opportunity to take appropriate corrective action prior to NIH's making a termination decision. NIH may decide to terminate the grant if the grantee does not take appropriate corrective action during the period of suspension. However, 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/HHS grant appeals procedures (see "Administrative Requirements—Grant Appeals Procedures"). NIH may award a replacement grant for a limited period of time (up to 18 months) without competition pending the outcome of an appeal or other action by the grantee.

A grant may also 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 origi-

nally 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 "Allowability of Costs/Activities—Selected Items of Cost" for the allowability of termination costs. Allowability of these costs does not vary whether a grant is terminated for cause by NIH, terminated by the grantee, or terminated by mutual agreement.

Withholding of support is a decision not to make a noncompeting continuation award within the current competitive segment. Withholding may occur for one or more of the following reasons:

- A grantee is delinquent in submitting required reports.
- Adequate Federal funds are not available to support the project.
- A grantee fails to show satisfactory progress in achieving the objectives of the project.
- A grantee failed to meet the terms of a previous award.
- A grantee's management practices fail to provide adequate stewardship of Federal funds.
- Any reason that would indicate that continued funding would not be in the best interests of the Government.

If a noncompeting continuation award is denied (withheld) because the grantee failed to comply with the terms and conditions of award in a previous budget period, 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, including civil action. Suspension under 45 CFR Part 76 is a distinct action from "suspension" as a postaward remedy described under "Suspension, Termination, and Withholding of Support" above. The subject of debarment and suspension as an eligibility criterion is addressed in the "Completing the Preaward 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 IC within a reasonable period of time after the demand, the IC 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 Government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by grantees (see also HHS claims collection regulations at 45 CFR Part 30). Debts may result from 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 at the higher of the Current Value of Funds Rate or the private consumer rate of interest fixed by the Department of the Treasury. A higher rate may be charged if necessary to protect the interests of the Government. Penalties and administrative collection costs will also be charged in accordance with the Act and the implementing HHS regulations, as follows:

- A penalty charge of six 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 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 a monetary adverse 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 grants as soon as possible after expiration of a grant that will not be extended or after termination of a grant as provided in 45 CFR 74.71 to 74.73 or 92.50. Closeout includes 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

Grantees are required to submit a final Financial Status Report, Final Invention Statement and Certification, and final progress report within 90 days of the end of grant support unless an extension is granted by the GMO. Failure to submit timely 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.

- Awards, including awards under SNAP, that will not be competitively 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 prior to termination. Final FSRs must have no unliquidated obligations, and must indi-

cate 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 responsibility of the grantee 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 may not be appealed (see "Administrative Requirements—Enforcement Actions—Recovery of Funds").

Where 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 charges must represent allowable costs under the provisions of the grant.
- There must have been an unobligated balance for the given budget period that is sufficient to cover the additional claim. Such a claim may be considered regardless of whether the unobligated balance was moved forward to offset the award for a subsequent budget period.
- Funds must be available from the applicable appropriation.

Final Progress Report

The final progress report should include, at a minimum, a summary of progress toward the achievement of the originally stated aims, a list of the results (positive or negative) considered significant, and a list of publications. 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 an invention(s) results from work under the grant. The final invention statement/certification must be signed by the PI and an authorized institutional official and must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, from the original effective date of support through the date of expiration or termination, whether or not previously reported. If there were no inventions, the statement should indicate "None."

Grant Appeals Procedures

HHS permits grantees to appeal certain postaward adverse administrative decisions made by HHS officials to an HHS Grant Appeals Board (see 45 CFR Part 16). NIH has established a first-level grant appeal procedure for discretionary grants and cooperative agreements that must be exhausted before an appeal may be filed with the HHS Departmental Appeals Board (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 such assistance 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 noncompeting continuation award under the project period system of funding 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 adverse determination letter, 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 except that, if the grantee can show good cause why an extension is warranted, an extension may be granted (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 Departmental Appeals Board (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, as it will review only appeals that have been reviewed and acted on by NIH.

In addition to the adverse determinations cited above, the DAB is the single level of appeal for disputes related to the establishment of F&A 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 negotiated special rates).[10] The grantee will be advised of any adverse determinations in these areas by the Division of Cost Allocation.

[10] The determination leading to such disputes may be made by an HHS official other than the GMO and may affect NIH grants as well as other HHS grants.

Part III: Terms and Conditions for Specific Types of Grants, Grantees, and Activities

Table of Contents

This Part includes terms and conditions that vary from the standard terms and conditions in Part II of this policy statement because of the type of grant, grantee, or grant-supported activity. There are separate sections for:

- Construction grants, including large-scale alteration and renovation (A&R) activities under grants with specific statutory authority for construction or modernization activities. (This section also includes requirements for certain A&R activities under nonconstruction grants);
- Individual and Institutional National Research Service Awards (NRSA) (also termed "fellowships" and "training grants");
- Conference grants;
- Consortium agreements;
- Grants to foreign and international organizations and domestic grants with a substantial foreign component;
- Grants to Federal institutions and payments to (or on behalf of) Federal employees under grants;
- Grants to for-profit organizations; and
- Research patient care activities.

These terms and conditions may apply in addition to, or in lieu of, those in Part II of this policy statement. Each section of this Part specifies how the coverage relates to that in Part II.

CONSTRUCTION GRANTS

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

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

For purposes of this section, "construction" and "modernization" are defined as follows:

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

"**Modernization**" means the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment necessary to make a building suitable for use for the purposes of a particular program.

Eligibility

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

Review and Approval

Construction grant applications are peer reviewed. NIH makes review and selection decisions using the following criteria/factors:

- Scientific merit of the research program activities that will be carried out in the proposed facility;
- NIH programmatic relevance;
- Research and financial need for the project;
- Scientific or professional standing or reputation of the applicant and of its existing or proposed officers and research staff;
- Relationship to the applicant's overall research programs and impact on relevant research programs and facilities in the geographic area and nationwide;
- The availability, by affiliation or other association, of other scientific or health personnel and facilities for carrying out the proposed research program, including, when warranted, the adequacy of a biohazard control and containment program; and
- The project cost and design.

Public Policy Requirements and Objectives

In addition to the public policy requirements and objectives specified in Part II, construction grants are subject to the following public policy requirements. Questions about whether a particular requirement applies to A&R activities under nonconstruction grants should be directed to the IC GMO. Grantees receiving construction grants must also require contractors and subcontractors providing construction services to comply with

certain Federal labor standards. These labor standards are discussed in "Equal Employment Opportunity, Labor Standards, and Other Contract Requirements" in this section.

The National Environmental Policy Act of 1969

The National Environmental Policy Act (NEPA), as amended (Public Law 91-190), establishes national policy goals and procedures to protect and enhance the environment, including protection against natural disasters. NEPA requires all Federal agencies to consider the probable environmental consequences of any major Federal activity, including grant-supported activities. To comply with NEPA for its grant-supported activities, NIH requires the environmental aspects of construction grants, and certain requests for financial assistance involving nonconstruction projects, to be reviewed and evaluated by NIH technical staff prior to final action on the application. With respect to earthquakes, structures will be evaluated in accordance with the lateral forces provisions of the Uniform Building Code.

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

Public Disclosure

Section 102 of NEPA and Executive Order 11514 (March 5, 1970) provide for public comment and participation in the environmental impact review process. Applicants are required to publicly disclose the project by publication in a newspaper or other publicly available medium and to describe its environmental impact concurrent with notification to the State Single Point of Contact (see "Intergovernmental Review under Executive Order 12372" in this section). An example of a suitable disclosure statement follows:

> "Notice is hereby given that the Uptown Medical School proposes to construct additional space, partially utilizing Federal funds. The proposed construction project is the addition of 2,700 square feet connected to the existing Allen Building, which is located at 5333 Main Street, Downtown, Ohio.
>
> The Medical School has evaluated the environmental and community impact of the proposed construction. There will be construction noise and increased construction traffic during the construction period. No significant permanent environmental impacts are foreseen. All building permits and zoning approvals have been obtained. In accordance with Executive Order 11514 (March 5, 1970), which implements the National Environmental Policy Act of 1969, as amended, any individual or group may comment on, or request information concerning, the environmental implications of the proposed project. Communications should be addressed to the Office of Planning, Uptown Medical School, and be received by (date). The Federal grant application may be reviewed at the Office of the Dean, School of Medicine, 5333 Main Street, during normal working hours."

Flood Insurance

The Flood Disaster Protection Act of 1973, as amended (Public Law 93-234), provides that no Federal financial assistance to acquire, modernize, or construct property may be provided in identified flood-prone communities in the U.S. unless the community participates in the National Flood Insurance Program and flood insurance is purchased within 1 year of the identification. The flood insurance purchase requirement is applicable to both public and private applicants for NIH support. Listings of flood-prone areas that are eligible for flood insurance are published in the *Federal Register* by the Federal Emergency Management Agency (FEMA).

Historic Properties and Archeological Sites

Under the provisions of section 106 of the National Historic Preservation Act, as amended, and the Historical and Archeological Preservation Act of 1960, as amended, the Secretary of the Interior has compiled a national register of sites and buildings of significant importance to U.S. history.[1] These requirements apply to all construction grants and may also apply to other NIH grant-supported activities, as specified by NIH.

The applicant must determine whether activities using NIH financial assistance will affect a property listed in the National Register. If a designated historic property is to be affected, the applicant must obtain clearance from the appropriate State Historic Preservation Office before submitting the application. Failure to obtain this clearance, if required, will delay NIH action on an application. The State Historic Preservation Liaison Officer or National Trust for Historic Preservation may be contacted for additional details.

[1] This listing may be obtained from the State Liaison Officers designated by their respective States to administer this program or from the Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW, Washington, DC 20004, (202) 606-8503. The National Trust for Historic Preservation is located at 1785 Massachusetts Avenue, NW, Washington, DC 20036, (202) 673-4000.

Intergovernmental Review Under Executive Order 12372

Executive Order 12372, Intergovernmental Review of Federal Programs (July 14, 1982), requires consultation with State and local officials on certain proposed Federal assistance. NIH construction grants are subject to these requirements, as implemented by 45 CFR Part 100, Intergovernmental Review of Department of Health and Human Services Programs and Activities. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert the SPOC to the forthcoming application and to obtain necessary instructions on the State process (see application material or **http://www.hhs.gov/progorg/grantsnet/laws-reg/spoq0695.htm** for a listing of the SPOCs). The SPOC is given 60 days to review the application. To accommodate this time frame and the NIH review process, an applicant must provide a copy of the application to the SPOC no later than the time the application is submitted to NIH. SPOC comments must be submitted with the application to NIH, or the application must indicate the date on which the application was provided to the SPOC for review. If SPOC comments are not submitted with the application, the applicant must provide them upon receipt and may include its reaction to the comments, or must notify NIH that no SPOC response was received.

Metric System

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

Relocation Assistance and Real Property Acquisition

The Uniform Relocation Assistance and Real Property Acquisition Policy Act of 1970 (the Uniform Act), 42 U.S.C. 4601 et seq., applies to all programs or projects undertaken by Federal agencies or with Federal financial assistance that cause the displacement of any person.

The HHS regulations and procedures for complying with the Uniform Act are set forth in 49 CFR Part 24. The rules at 49 CFR Part 24 provide uniform policies and procedures for the acquisition of real property, including acquisition by grantees, and require that displaced persons are treated fairly and equitably. The regulations encourage acquiring entities to negotiate with property owners in a prompt and amicable manner so that litigation can be avoided and property owners' interests are protected.

Other Public Policy Requirements

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

- Clean Air Act, 42 U.S.C. 7401 et seq., and Federal Water Pollution Control Act, as amended, 33 U.S.C. 1251 et seq., for contracts exceeding $100,000.
- Uneconomical, hazardous, or unnecessary use of flood plains for construction—Executive Order 11988 (May 24, 1977).
- Provisions for potable water supply—Safe Drinking Water Act (Title XIV of the Public Health Service Act, as amended).
- Conservation of vital energy resources (gas, oil, electricity, etc.)—Facility design will be evaluated on the basis of American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE) standards for energy conservation.
- Conservation of petroleum and natural gas—Executive Order 12185 (December 17, 1979).

Other Design Requirements for NIH-Assisted Construction[2]

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

Where State or local codes are proposed to be used as a basis for facility design in lieu of the NIH design requirements, a prior determination must be made by NIH that the specific State or local code is equivalent to, or exceeds, NIH requirements. If State and local codes or requirements exceed the design requirements set forth in NIH regulations or incorporated in program guidance, the more stringent requirements will

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

apply. NIH will also monitor compliance during the design phase of the project.

Elimination of Architectural Barriers to the Physically Handicapped

The Architectural Barriers Act of 1968, as amended, the Federal Property Management Regulations 101-19.6 (41 CFR 101-19.6), and the Uniform Federal Accessibility Standards issued by the General Services Administration (41 CFR 101-19.6, Appendix A) set forth requirements to make facilities accessible to, and usable by, the physically handicapped and include minimum design standards. All new facilities constructed with NIH grant support must comply with these requirements. These minimum standards must be included in the specifications for any NIH-funded new construction unless the grantee proposes to substitute standards that meet or exceed these standards. Where NIH assistance is provided for alteration or renovation (including modernization and expansion) of existing facilities, the altered facility (or part of the facility) must comply, including use of the minimum standards in the specifications. The grantee will be responsible for conducting inspections to ensure compliance with these specifications by any contractor performing construction services under the grant. See also "Public Policy Requirements and Objectives—Civil Rights—Rehabilitation Act of 1973" in Part II.

Guidelines for Design and Construction of Hospital and Healthcare Facilities (1996-97)

Available from the American Institute of Architects (AIA), Academy of Architecture for Health, AIA Rizzoli Catalogue Sales, 117 Post Street, San Francisco, CA 94108; telephone: 1-800-52-BOOKS; fax: (415) 984-0224.

American Society of Heating, Refrigeration, and Air Conditioning Engineers Handbook—HVAC Applications (1995)

Available from the American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE), 1791 Tullie Circle, NE, Atlanta, GA 30329; telephone: (404) 636-8400 or, for order questions, 1-800-527-4723.

Seismic Safety for Federally Assisted Construction

The Earthquake Hazards Reduction Act of 1977, as amended (Public Law 95-124), and Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990). The Executive Order requires that new federally assisted or regulated buildings are to be designed and constructed using appropriate seismic standards. State, county, or local jurisdictional building ordinances adopting and enforcing these model codes, in their entirety or without material revisions reducing the level of seismic safety, are also acceptable.

The latest editions of the model codes listed below provide a level of seismic safety considered appropriate for implementing Executive Order 12699 and apply to all federally assisted construction in the applicable geographic location.

- Uniform Building Code, International Conference of Building Officials (ICBO) (5360 Workman Mill Road, Whittier, CA 90601-2298; telephone: (562) 699-0541 or 1-800-284-4406; fax: 1-888-329-4226).

- 1998 Supplements to the National Building Code (1996) and National Fire Prevention Code (1996), Building Officials and Code Administrators International, Inc. (BOCA) (4051 West Flossmoor Road, Country Club Hills, IL 60478-5795; telephone: (708) 799-2300; fax: (708) 799-4981).

- Southern Building Code Congress Standard Building Code (1997) Southern Building Code Congress International (SBCCI) (900 Montclair Road, Bir-

mingham, AL 35213-1206; telephone: (205) 591-1853); fax: (205) 599-9845).

- Recommended Lateral Force Requirements and Commentary (1996), Seismology Committee, Structural Engineers Association of California (available from ICBO as indicated above).

Where necessary, special structural and other features to protect life and minimize damage to facilities from tornadoes may also be required.

Life Safety Code

National Fire Protection Association (NFPA) Publication No. 101 and supplements that apply for the code classification and type of occupancy of the particular facility. This document is available from NFPA, 11 Tracy Drive, Avon, MA 2322; telephone: (617) 770-3000 or 1-800-735-0100.

Standards on Fire Protection for Laboratories Using Chemicals

National Fire Protection Association (NFPA) Publication No. 45. NPFA, 11 Tracy Drive, Avon, MA 02322; telephone: (617) 770-3000 or 1-800-735-0100.

Prudent Practices for Safety in Laboratories (1995)

National Research Council. National Academy Press, 2101 Constitution Avenue, NW, Lockbox 285, Washington, DC 20418; telephone: 1-800-624-6242.

National Sanitation Foundation Standard No. 49 for Class II (Laminar Flow) Biohazard Cabinetry (1992)

National Sanitation Foundation (NSF), 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, MI 48106; telephone: (313) 769-8010.

International Standard Plumbing Code (1996)

Southern Building Congress Code International (SBCCI), 900 Montclair Road, Birmingham, AL 35213-1206; telephone: (205) 591-1853; fax: (205) 599-9845.

Industrial Ventilation: A Manual of Recommended Practice (1998)

American Conference of Government Industrial Hygienists (ACGIH), 1330 Kemper Meadow Drive, Cincinnati, OH 45240-1634; telephone: (513) 742-2020; fax: (513) 742-3355.

Health Care Facilities Handbook (1997)

National Fire Protection Association (NFPA), 11 Tracy Drive, Avon, MA 02322; telephone: (617) 770-3000 or 1-800-735-0100.

Standards for Nonflammable Medical Gas Systems

National Fire Protection Association (NFPA) Publication No. 99 (at the address and telephone number above).

National Electric Code

National Fire Protection Association (NFPA) Publication No. 70. (at the address and telephone number above).

Laboratory Ventilation Workbook (1994)

D. Jeff Burton, American Industrial Hygiene Association (AIHA), 2700 Prosperity Avenue, Suite 250, Fairfax, VA 22031; telephone: (703) 849-8888; fax: (703) 207-3561.

Funding

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

Matching

NIH construction grants generally require the grantee to share in the costs of the project. This requirement, if applicable, is stated as a matching percentage, and the grantee's match is usually at least 50 percent of the total allowable project costs. Any required non-Federal participation may be in the form of allowable costs incurred by the grantee or a contractor under the grant. Unless required by statute or regulation, NIH does not generally allow grantees to use the value of third party in-kind contributions as a source of matching. Matching funds and in-kind contributions (if authorized) must meet the allowability and documentation requirements of 45 CFR 74.23 or 92.24, as applicable. These costs/in-kind contributions are subject to the same requirements in 45 CFR Part 74 or 92, the applicable cost principles, and this policy statement, as if the grantee were spending NIH funds.

The source and amount of funds proposed by an applicant to meet a matching requirement must be identified in the application. The applicant will be required to demonstrate that the funds are committed or available prior to award. This may take the form of a certification as specified by the awarding IC. The amount of NIH (Federal) funds awarded, combined with the non-Federal share , will constitute the total approved budget as shown in the NGA. The prior approval and other dollar thresholds contained in this section are determined on the basis of the total approved budget unless otherwise specified.

Allowability of Costs/Activities

Construction activity is allowable only when the program legislation includes specific authority for construction, modernization, or significant alteration and renovation of facilities, and NIH specifically authorizes such costs. The following listing indicates types of costs and activities generally allowable and unallowable under NIH construction grants. This list is not all-inclusive. Program guidelines and other terms and conditions of the award should be consulted for the specific costs allowable under a particular program or grant.

Allowable Costs/Activities

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

  A&R costs of this type associated with a building under construction or an otherwise incomplete structure may be allowed if:
  - The space is to be adapted to particular program needs,
  - It is cost-effective to perform the work while the building is being constructed or the structure is being completed, and
  - A&R costs are limited to the difference between the cost of completing the interior space for general use and the cost of adapting the space and

utilities to meet specific program requirements.

When the grantee's own construction and maintenance staff is used in carrying out the A&R (i.e., force account), the associated costs are allowable provided the grantee can document that force account is less expensive than contracting, and all costs are substantiated by appropriate receipts for the purchase of materials and certified pay records for the labor involved.

- Architectural and engineering services.
- Bid advertising.
- Bid guarantees, performance and payment bonds (in accordance with 45 CFR 74.48 or 92.36(h)).
- Contingency fund: Applicants for construction grants may include a project contingency fund in initial cost estimates to provide for unanticipated charges. These funds will be limited to 5 percent of construction and equipment costs before bids are received and must be reduced to 2 percent after a construction contract has been awarded.
- Filing fees for recording the Notice of Federal Interest (see "Real Property Management Standards—Notice of Federal Interest" in this section).
- Inspection fees.
- Insurance: Costs of title insurance, physical destruction insurance, and liability insurance are generally allowable. Physical destruction and liability insurance are usually treated as F&A costs but may be treated as direct costs in accordance with the established policy of the grantee, consistently applied regardless of the source of funds. Title insurance, if required, may be charged to the grant in proportion to the amount of NIH (Federal) participation in the property (see "Real Property Management Standards—Insurance Requirements" in this section).
- Legal fees related to obtaining a legal opinion regarding title to site.
- Preaward costs: Costs incurred before an award for architect's fees and consultant's fees necessary to the planning and design of the project are allowable if the project is subsequently approved and funded.
- Project management.
- Relocation expenses.
- Sidewalks necessary for use of facility.
- Site survey and soil investigation.
- Site clearance (as long as reflected in bid).

Unallowable Costs/Activities

- Bonus payments to contractors, including guaranteed maximum price contractors.
- Construction of "shelled" space designed for completion at a future date.
- Consultant fees not related to actual construction.
- Damage judgment suits.
- Equipment purchased through a conditional sales contract.
- Fund-raising expenses.
- Land acquisition.
- Legal services not related to site acquisition.

- Movable equipment.
- Off-site improvements.
- Relocation of utilities.

Procurement Requirements for Construction Services under NIH Construction Grants

General

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

In general, grantees must:

- Ensure that all qualified contractors are given an opportunity to bid and have their bids fairly considered.
- Guarantee, insofar as possible, that the contract(s) will result in the completion of a facility (ready for occupancy) that conforms to the design and specifications approved by the NIH awarding office (or any appropriate modification thereof with NIH awarding office approval, as required) at a cost that is within the owner's ability to pay (the term "owner" refers to the legal entity that holds (or will hold) title to the property on which the grant-supported construction is performed and is generally the applicant or grantee).
- Obtain NIH awarding office approval of plans and specifications both before bids or proposals are solicited and before the award of a prime construction contract. The procurement methods to be employed must be reviewed and approved by the NIH awarding office. The grantee (owner) is responsible for ensuring that the project is constructed to completion in accordance with the approved plans or specifications and for obtaining necessary approvals for changes as specified in this section.
- The grantee (owner), including the firms acting for it in a professional capacity, must take adequate steps to ensure that the total cost of all contracts, i.e., total cost of construction, awarded under a project will be within the amount of funds available for the project. This can be accomplished by accurate price estimating and/or the use of bid alternates. A precise description of the scope of work, specifications, materials, and construction techniques in the invitation for bids will facilitate accurate cost estimating by both the bidder and the grantee's (owner's) professional representatives. The description of work becomes especially important when multiple contracts will be let in support of the same project, since each contractor must know exactly what is involved in the portions of the job on which he or she is bidding. Invitations for bids must stipulate a time for completion of the project, expressed either in calendar days or as a fixed date, for each prime contract to be awarded under the project.

Where more than one NIH or HHS program will support a construction project, or where the NIH-supported project is less than the entire facility or construction to be bid, the grantee must obtain bids that provide, to the maximum extent possi-

ble, the costs for that portion of the total job that will be financed by NIH funds and any required grantee matching. This may be done by (1) showing the cost for each building or site in the project, if it consists of more than one building or construction site and can be divided for bidding and construction purposes, or (2) identifying, to the extent possible, or prorating the applicable costs when the project is a single site or contains common space and cannot be divided for bidding and construction purposes.

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

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

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

- If a construction management firm is currently employed by the grantee (owner), authorize that firm to perform the construction work after obtaining NIH awarding office prior approval. The price for the work involved must not exceed the line-item prices stipulated in the construction management contract (guaranteed maximum price) as approved by the NIH awarding office (see "Construction Management Services" in this section for requirements for a construction management agreement).

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

Construction Management Services

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

Contracting for construction work on a project covered by a construction management agreement is subject to all of the requirements otherwise applicable to the solicitation and award of contracts, except that bids may be obtained by prequalification and selective solicitation. When prequalification and selective solicitation are used, the construction manager must (1) prequalify all firms that respond to the announcement and are determined to meet the prequalification standards; (2) establish bidders lists for each of the invitations for bids, including, at least, all firms qualified in (1), and possibly including other known qualified firms; (3) solicit, in writing, bids from all firms on the bidders list; (4) consider bids from any contractor who requests permission to bid and who is determined by the grantee (owner) to meet the prequalification standards; and (5) prepare a bid abstract.

Guaranteed maximum price (GMP) is not the preferred method of award for construction management services under NIH grants. The grantee shall obtain NIH prior written approval to use this method. If use of this method is approved, the grantee must comply with the following requirements:

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

- The GMP must be obtained from the construction manager before NIH will authorize the solicitation and award of the first construction contract. This requirement shall apply whether or not phased construction techniques are employed. Each portion of the work for which a separate contract is expected to be let shall be separately priced as an individual line item in the GMP contract.

The grantee shall transmit all GMP bids to the IC GMO, with a recommendation for award to the lowest responsive responsible bidder.

After the competitive award of a GMP contract, the following shall apply:

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

- All GMP bids must be completely itemized by trade to include a separation of labor and materials, all markups, and no contingency other than that which will cover change order items as approved by the grantee.

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

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

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

Design-Build Services

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

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

- Technical considerations as well as cost may be treated as competitive factors;
- The grantee (owner) may negotiate cost or design with one or any number of firms.

On all design-build projects, the owner must ensure a firm total cost by including in the design-build contract a provision that extra costs resulting from errors or omissions in the drawings or estimates will be the design-build firm's responsibility.

Equal Employment Opportunity, Labor Standards, and Other Contract Requirements

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

Equal Employment Opportunity

Construction contracts (and subcontracts) awarded under NIH grants are subject to the requirements of Executive Order 11246 (September 24, 1965), as amended, as implemented in 41 CFR Part 60-1 by the Office of Federal Contract Compliance Programs (OFCCP), U.S. Department of Labor. The grantee is required to include the "Equal Opportunity Clause" at 41 CFR 60-1.4(b) in any construction contract exceeding $10,000 under the grant. The contractor must be directed to include this clause in any applicable subcontracts.

In addition, grantees and construction contractors under NIH grants are required to comply with the solicitation and contract requirements for affirmative action specified in 41 CFR Part 60-4 for contracts that will exceed $10,000 in designated geographical areas. These requirements are specified in the "Notice of Requirement for Affirmative Action To Ensure Equal Employment Opportunity (Executive Order 11246)" and the "Standard Federal Equal Employment Opportunity Construction Contract Specifications (Executive Order 11246)."

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

Further information about these requirements and the full text of these regulations is available at **http://www.dol.gov:8002/ofccp/wren/ofccp.htm**.

Non-Segregated Facilities

Pursuant to 41 CFR 60-1.8, the grantee shall require each prospective construction contractor for a contract that will exceed $10,000 to submit a certification that the contractor does not, and

will not, maintain any facilities it provides for its employees in a segregated manner, or permit its employees to perform their services at any location, under the contractor's control, where segregated facilities are maintained, and the contractor will obtain a similar certification prior to the award of any covered subcontract.

Labor Standards

Contract Work Hours and Safety Standards Act

Construction contractors and subcontractors with contracts/subcontracts exceeding $100,000 under NIH grants are subject to the requirements of the Contract Work Hours and Safety Standards Act, 40 U.S.C. 327-333, concerning the payment of overtime and the maintenance of healthful and safe working conditions.

Wages paid any laborer or mechanic employed by the contractor or subcontractor must be computed on the basis of a standard workweek of 40 hours. For all work in excess of the standard workweek, mechanics and laborers shall be compensated at a rate not less than one-and-a-half times the basic rate of pay. If this requirement is violated, the contractor or subcontractor is liable to the employee for the unpaid wages and may be liable to the Government for liquidated damages. NIH or the grantee may withhold otherwise payable funds to satisfy any such liability. The statute also specifies penalties for intentional violation of these requirements.

Further, no contractor or subcontractor under an NIH grant shall require any laborer or mechanic employed in the performance of the contract to work in surroundings or under working conditions that are unsanitary, hazardous, or dangerous to an individual's health or safety, pursuant to standards issued by the Secretary of Labor. Violation of these requirements may be cause for debarment from future Federal contracts or financial assistance.

Liquidated Damages

Invitations for bids must stipulate a time for completion of the project, expressed either in calendar days or as a fixed date, for each prime contract to be awarded under the project.

At the option of the grantee (owner), a liquidated damages provision may be included in the construction contract, allowing for assessment of damages when the contractor has not completed construction by the date specified in the contract. Liquidated damages must be real and justified and must be approved by NIH prior to solicitation. Where there is an assessment of damages, any amounts paid belong to the owner.

Disposition of Unclaimed Wages

If it is discovered, either during or after the period of performance of an NIH-assisted construction contract, that an employee is entitled to wages but cannot be located for the purposes of payment (or for some reason refuses to accept payment), the grantee may eventually have to repay the Federal Government. Therefore, NIH suggests that the contractor be required to turn over any unclaimed wages to the grantee.

The grantee should notify the GMO that an escrow account has been established in the affected employee's name and should maintain the account for a period of either 2 years following the completion of the contract or such longer period as may be required by State or local law. Upon the expiration of this period, any amounts still unclaimed will be disbursed by refunding to NIH either the entire amount, if the construction project was 100 percent funded by NIH, or an amount representing the percentage of NIH participation in the project. In the event the project was funded by more than one NIH or HHS program at differing rates, the percentage on which the refund is based should be an average percentage calculated by weighting each program's rate of participation by the dollar amount of that program's contribution.

If the contractor has made a reasonable effort to locate the employee by having mail forwarded and contacting the employee's union, the grantee

need not repeat such attempts. If there is reason to believe that the contractor's efforts to locate employees that are due wages were not thorough, the grantee should attempt to locate the employees. Doing so will reduce the likelihood of future claims against the grantee.

If any wages held in escrow are paid to an employee or an employee's legal representative during the period in which the account is maintained, a complete report must be made to the IC GMO when the account is closed.

Administrative Requirements

Prior Approval Requirements

Construction Grants

Grantees (owners) must obtain written prior approval from the IC GMO for grantee-initiated changes in project or budget as follows:

- A revision that would result in a change in scope or objectives of the project, including proposed modifications that would materially alter the costs of the project, including unit costs, space utilization, or financial layout, and resulting changes in the previously approved solicitation or contract.
- A revision that would increase the amount of Federal funds needed to complete the project.
- Any other applicable change as specified in "Administrative Requirements—Changes in Project and Budget." Construction grants are not eligible for expanded authorities.

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

Alteration and Renovation Projects under Nonconstruction Grants

Two copies of each of the following documents are to be submitted with each request for approval of A&R costs greater than $300,000, but not more than $500,000, (whether proposed in the application or as a postaward rebudgeting request):

- A single line drawing of the existing space and proposed alterations.
- A narrative description of the proposed functional utilization of the space and equipment requirements prepared by the program and administrative managers who will use and be responsible for the working space and, when appropriate, with input from architectural and engineering advisors. Final drawings and specifications will be based on this description.
- The description shall include a detailed explanation of the need, character, and extent of the functions to be housed in the space proposed for A&R, using the following headings, as appropriate:
  - General information,
  - Description of the functions to be performed in the space,
  - Space schedule (detailed description of floor space),
  - List of fixed equipment proposed for the facility,
  - Cost estimate (see sample format in Exhibit 1),

- Special design problems,
- Description of the existing and proposed utility systems for the modified space,
- Description of plans to provide accessibility for the physically handicapped,
- Provisions for meeting the requirements of the Life Safety Code,
- The length of the property lease if the space is rented, and
- Other information required by program legislation or regulations.

When the proposed alteration is to occur in a building that is under construction or in an incomplete structure, two copies of the following documentation must also be provided:

- A detailed justification for the need to perform the work before the building is completed,
- A cost comparison between doing the work before and after the building is completed, and
- A description of other specific benefits to be gained by doing the work before the building is completed.

Applicants/grantees undertaking A&R projects that will require NIH funding of more than $500,000 are subject to the review, approval and documentation requirements included or referenced in this section for construction grants.

Real Property Management Standards

General

In addition to any program-specific or project-specific requirements imposed by the terms of the award, real property constructed under an NIH grant-supported project is subject to the requirements of 42 CFR Part 52b, in addition to the provisions of 45 CFR 74.30 through 74.32 and 74.37 or 92.31, as applicable, regarding use, transfer of title, and disposition.

Real property constructed or renovated with NIH grant support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the grantee, except as expressly authorized in writing by NIH. In the event of any default of any description under a mortgage on the part of a grantee, the grantee shall immediately provide the awarding office GMO with both telephonic and written notification of the default.

The mortgage agreement shall:

- Specifically allow, in the case of default, that NIH or its designee may assume the role of mortgagor and continue to make payments;
- Provide that, in the event NIH (or its designee) chooses not to assume the role of mortgagor in the case of default, the mortgagee shall pay NIH an amount equal to the share of the sales proceeds otherwise due the grantee (mortgagor) multiplied by the Federal (i.e., NIH) share of the property; and
- Provide that the mortgagee notify NIH at least 30 days prior to initiating foreclosure action.

Any NIH assignment of the property and mortgage responsibilities to any party, other than NIH, shall be subject to prior approval of the mortgagee.

Use and Disposition

The governing statute for the construction grant program may contain usage and disposition requirements for real property constructed or renovated under a grant that are in addition to or different from the usage and disposition require-

ments of 42 CFR 52b and 45 CFR 74.32 or 92.31, as applicable. These may include provisions governing the length of the grantee's accountability obligations, the Federal right of recovery, or waivers. In those cases, to the extent the statutory provisions are inconsistent with the requirements of 42 CFR Part 52b and/or 45 CFR Part 74 or 92, including those described in this subsection, the statutory provisions, as reflected in the terms and conditions of the award, will apply.

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

For disposition of property acquired on an amortized acquisition basis, the formulas in 45 CFR 74.32 and 92.31 do not apply in determining the Federal share. In cases of amortized acquisition, the Federal share will be determined by multiplying the amount of mortgage principal already repaid at the time of disposition by the average Federal participation (taken from the Financial Status Report) plus the increase in value over the purchase price multiplied by the average Federal participation plus the Federal participation in the down payment. The computation of the Federal share of real property acquired with long-term debt financing must be computed for each year of grant support in which Federal funds are used to meet all or a portion of the down payment and/or principal on the mortgage.

Real Estate Appraisals

If a real estate transaction funded in whole or in part by NIH requires the use of a real estate appraisal (including, but not limited, to appraisals to determine the Federal share of real property and appraisals to determine required insurance levels), the appraisal must be performed by appraisers certified or licensed by the applicable State in accordance with the requirements established by Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA), as amended (Public Law 101-73).

Notice of Federal Interest

In order to protect the Federal interest in real property that has been constructed or renovated with NIH construction grant funds, grantees shall record a lien or other related notice of record (Notice of Federal Interest) in the appropriate official records of the jurisdiction in which the property is located. The time of recordation shall be when construction or renovation begins. Fees charged for recording the Notice of Federal Interest may be charged to the grant (see "Allowability of Costs/Activities—Allowable Costs/Activities" in this section).

Insurance Requirements

Immediately upon completion of construction, nongovernmental grantees shall, at a minimum, provide the same insurance coverage as provided for other property they own. "Completion of construction" means either the point at which the builder turns the facility over to the grantee (e.g., the date of the final acceptance of the building) or the date of beneficial occupancy, whichever comes first. Federally owned property provided to a grantee for use need not be insured.

If title vests in the grantee, the following coverage is required as the minimum insurance coverage for real property acquired with NIH grant funds:

- A title insurance policy that insures the fee interest in the real property for an amount not less than the full appraised value of the property. When the Federal

participation in the construction of real property covers only a portion of a building, title insurance should cover the total cost of the facility in order to prevent liens on the unsecured portion from having an adverse impact on the portion with a Federal interest. In those instances where the grantee already owns the land, such as a building being constructed in the middle of a campus setting, in lieu of a title insurance policy, the grantee may provide evidence satisfactory to the NIH awarding office, such as legal or title opinion, that it has good and merchantable title free of all mortgages or other forecloseable liens to all land, rights of way, and easements necessary for the project. In instances where a grantee is given land by the State, if the State recently acquired the land in a land swap transaction, the grantee that is then given the land should obtain title insurance. However, if the State has owned the land for a considerable period of time, title insurance would not be necessary, and a copy of the State documents giving the land to the grantee would be sufficient. If the grantee must buy the land on which to build, a legal opinion would not be sufficient, and title insurance must be obtained in order to protect the Federal interest in the building to be constructed.

- A physical destruction insurance policy that insures the full appraised value of the facility from risk of partial and total physical destruction. When the Federal participation in the construction or renovation of real property covers only a portion of a building, the insurance should cover the total cost of the facility, because any damage to the building could make the building unusable and could thus affect the Federal interest. The insurance policy is to be maintained for the duration of the Federal interest in the property (usually 20 years) (see "Real Property Management Standards—Use and Disposition" in this section). The cost of insurance coverage after the period of grant support must be borne by a source other than the grant that provided the funds for the construction or renovation. The grant account will not remain open for this purpose.

Within 5 days of completion or beneficial occupancy, the grantee shall submit, to the GMO, a written statement signed by the authorized institutional official certifying that the grantee (1) has purchased the required insurance policies on the NIH-funded facility, and (2) will maintain the insurance coverage at the full appraised value of the facility throughout the period of Federal interest as specified in the NGA.

The awarding office may waive one or both of the requirements above upon a showing that the grantee is effectively self-insured against the risks involved. The term "effectively self-insured" means that the grantee has sufficient funds to pay for any damage to the facility, including total replacement if necessary, or to satisfy any liens placed against the facility. If the grantee claims self-insurance, the grantee must provide to NIH a certification that it has sufficient funds available to replace or repair the facility or to satisfy all liens. This certification should state the source of the funds, such as the institution's endowment or other special funds set aside specifically for this purpose.

EXHIBIT 1

ALTERATION AND RENOVATION COST ESTIMATE OUTLINE

This is a suggested format and is not to be construed as a required form.

Estimate the costs in which the Federal Government is requested to participate

1.	**Demolition**	**$**_____
2.	**General alteration and renovation (e.g., carpentry, masonry, painting)**	**$**_____
3.	**Plumbing**	**$**_____
4.	**Heating, ventilation, and air conditioning**	**$**_____
5.	**Electrical**	**$**_____
6.	**Architect's and engineer's fees**	**$**_____
7.	**Other costs (specify)**	**$**_____
8.	**TOTAL A&R COSTS (To Federal Government)**	**$**_____
9.	**Fixed equipment**	**$**_____

EXHIBIT 1 (Continued)

LIST SOURCE AND AMOUNT OF FUNDS FOR TOTAL ALTERATION AND RENOVATION PROJECT:

NIH SOURCES AND AMOUNTS	**ALL SOURCES AND AMOUNTS OTHER THAN NIH**
_____	_____
_____	_____
_____	_____
_____	_____

Total gross square meters/feet of floor area in alteration and renovation proposal

_____

Estimated cost per gross square meter/foot excluding fixed equipment

$_____

Total net square meters/feet of floor area in alteration and renovation pr o-posal

_____

Estimated cost per net square meter/foot, excluding fixed equipment

$_____

NATIONAL RESEARCH SERVICE AWARDS

Applicability

This section is a self-contained document that includes the National Research Service Award (NRSA) guidelines for individual and institutional awards as originally published in the *NIH Guide for Grants and Contracts* Vol. 26, No. 21, June 21, 1997. It includes all requirements of NRSA awards and, therefore, should be followed by NRSA recipients in lieu of the coverage in Part II of this policy statement.

I. General

A. Background

Section 487 of the Public Health Service Act (42 U.S.C. 288), provides authority for the National Institutes of Health (NIH) to award National Research Service Awards (NRSA) to support predoctoral and postdoctoral training. This section states that the Secretary shall provide National Research Service Awards for predoctoral and postdoctoral training of individuals to undertake biomedical and behavioral research at domestic and foreign, public and private institutions (profit and non-profit). Section 487 (a) (1) (B) authorizes institutional NRSA grants limiting NRSA support to training and research at public and non-profit private entities. The National Research Service Award legislation requires recipients to pay back to the Federal Government their initial 12 months of NRSA postdoctoral support by engaging in health-related biomedical or behavioral research, research training, health-related teaching, or any combination of these activities (See Section IV below). Title 42 of the Code of Federal Regulations, Part 66, is applicable to these awards.

B. Nondiscrimination

The NIH research training and career development programs are conducted in compliance with applicable laws that provide that no person shall, on the grounds of race, color, national origin, handicap, or age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity (or, on the basis of sex, with respect to any education program or activity) receiving Federal assistance. Applicant organizations are required to have appropriate Assurance of Compliance forms filed with the Office of Civil Rights, Office of the Secretary, DHHS before a grant may be made to that institution. The NIH awarding office should be contacted if there are any questions concerning compliance.

II. Individual National Research Service Awards (Fellowships)

A. General

The Congress of the United States enacted the National Research Service Act Program in 1974 to help ensure that highly trained scientists would be available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Under this congressional authority, the NIH awards NRSA individual postdoctoral fellowships (F32) to the most promising applicants to support full-time research training related to the mission of the NIH ICs. Some specialized individual predoctoral fellowships (F31s and F30s) and Senior Fellowships (F33s) are also provided under the NRSA. For individual predoctoral fellowships, NIH awarding offices have different requirements. Thus specific program announcements should be consulted for guidance.

National Research Service Awards (NRSA) are made to individual fellowship applicants selected for award as a result of national competition for research training in specified health-related areas. All NIH ICs except the Fogarty International Center (FIC) and the National Library of Medicine (NLM) make individual awards under NRSA. FIC & NLM have unique funding authorities for fellowships that are not under the NRSA.

1. Eligibility

a. Research Areas

National Research Service Awards may be made for research training in areas which fall within the mission of the NIH ICs. Applications which do not fit these areas will be returned. An increased emphasis has been placed on the research training of physicians. The Secretary, DHHS, is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of two consecutive years of biomedical and behavioral research training.

b. Research Training Program

The NRSA fellowship must be used to support a program of research training. It may not support studies leading to the M.D., D.O., D.D.S., D.V.M., or other clinical, health professional degrees; nor to support residencies, the primary purpose of which is the attainment of a medical or nursing specialty. Research trainees in clinical areas are expected to devote full time to the proposed research training and to confine clinical duties to those which are part of the research training.

2. Degree Requirements

a. Predoctoral

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

b. Postdoctoral

Before an NRSA award can be activated, individuals must have received a Ph.D., M.D., D.O., D.D.S., D.V.M., O.D., D.P.M., Sc.D., D.Eng., D.N.S., or equivalent doctoral degree from an accredited domestic or foreign institution. Certification by an authorized official of the degree granting institution that all degree requirements have been met is also acceptable.

c. Senior Fellows

As of the beginning date of their award, senior fellows must have received a doctoral degree (as in A.2.b. above) and must have had at least seven subsequent years of relevant research and professional experience. The senior fellowship is awarded to provide opportunities for experienced scientists to make major changes in the direction of their research careers or to broaden their scientific background by acquiring new research capabilities. In addition, these awards will enable individuals beyond the new investigator stage to take time from regular professional responsibilities for the purpose of increasing their capabilities to engage in health-related research. Senior fellowships are made for full-time research training. Health professionals may utilize some of their time in clinical duties which are part of their research training.

3. Citizenship

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. A non-citizen national is a person, who, although not a citizen of the United States, owes permanent allegiance to the U.S. They are generally persons born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must be in possession of a currently valid Alien Registration Receipt Card (I-551), or must be in possession of other legal verification of such status. For example, if an individual is in possession of the proper validation on his/her passport, a notarized photocopy of the passport could suffice. Since there is a 6-month limitation on this validation, it is the responsibility of the sponsoring institution to follow-up and assure that the individual received the I-551 prior to the six month expiration date.

An individual expecting to be admitted as a permanent resident by the earliest possible award date listed in the fellowship program announcement may submit an application for an individual NRSA fellowship. The submission of documentation concerning permanent residency is not required as part of the initial application. Any applicant selected to receive an award must provide a notarized statement of admission for permanent residence prior to award.

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

Individuals on temporary or student visas are not eligible for support from the NRSA.

4. Sponsorship

a. General

Before submitting a fellowship application, the applicant must identify a sponsoring institution and an individual who will serve as a sponsor and will supervise the training and research experience. The sponsoring institution may be private (profit or non-profit) or public, including the NIH Intramural Programs and other Federal laboratories. The applicant's sponsor should be an active investigator in the area of the proposed research who will directly supervise the candidate's research. The sponsor must document in the application the training plan for the applicant as well as the availability of staff, research support, and facilities for high-quality research training. Applicants proposing training at their doctorate institution or at the institution where they have been training for more than a year must document thoroughly the opportunity for new training experiences that would broaden their scientific background.

b. Foreign Sponsorship

Under exceptional circumstances an individual may request support for training abroad. In such cases, the applicant is required to provide detailed justification for the foreign training and why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than training in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Only in cases where there are clear scientific advantages will the foreign training be considered for funding.

5. NIH Employees

Both Civil Service employees and PHS Commissioned Officers at NIH are permitted to compete for predoctoral and postdoctoral fellowships. The proposed training should be primarily for career development rather than for the immediate research needs of NIH. The employee's supervisor must disassociate him/herself from the review and award process.

Successful NIH applicants for the predoctoral or postdoctoral fellowship awards must either resign from NIH or take leave without pay prior to activating the award. (There is no obligation or commitment by NIH or the fellow for future employment at NIH upon termination of the fellowship.)

6. Individuals on Active Military Duty

NIH has no restriction against career military personnel applying for research fellowship awards while on active military duty. At the time of application, a letter from the applicant's branch of the military service should be submitted endorsing his/her application and indicating willingness to continue normal active duty pay and allowance during the period of the requested fellowship. If an award is made, the institutional allowance and necessary tuition and fees permitted on a postdoctoral program will be paid. However, stipends, health insurance, and travel allowances will not be reimbursed. Payment of

concurrent benefits by NIH to active duty career military awardees is not allowed.

B. Application and Receipt Dates

1. Application

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

Applicants and sponsoring institutions must comply with policies and procedures governing the protection of human subjects, the humane care and use of live vertebrate animals, and the inclusion of women, minorities and children in study populations.

On the application face page, applicants should indicate (in the Request for Applications section) the initials of the NIH Institute most appropriate to the research area of the application. If the application is submitted in response to a Program Announcement (PA) or Request for Application (RFA) from a particular Institute, the applicant should identify the number of the PA or RFA on the face page. This information will be used as a guide in the application assignment process.

2. Concurrent Applications

An individual may not have two or more competing NRSA applications pending review concurrently in the National Research Service Award program.

3. Application Availability

Application kits containing forms, instructions, and related information may be obtained from:

The Division of Extramural Outreach and Information Resources, OER, NIH
Rockledge II, Suite 6095, MSC 7910
Bethesda, MD 20892-7910
Phone: (301)-435-0714
E-mail: grantsinfo@od.nih.gov

4. Receipt Dates

Individual fellowship applications undergo a review process that takes between five and eight months. The annual receipt dates and review cycle are found in Appendix 2.

C. Review

Each initial and competing renewal application will be evaluated for scientific merit by an NIH Scientific Review Group (SRG). Review criteria for this evaluation will include the applicant's past academic and research record, the research training proposal, the sponsor's general qualifications, the training environment, publications, references, and the applicant's research goals. Individual fellowship applications receive a secondary level of review by Institute staff.

It is important to remember that the purpose of the fellowship program is for research training. Major considerations in the review are the applicant's potential for a productive scientific career, the applicant's need for the proposed training, and the degree to which the research training proposal, the sponsor, and the environment will satisfy these needs.

D. Notification of Action

Shortly after the initial review meeting, each candidate receives a mailer that includes the SRG recommendation/priority score and the name of a program official in the assigned NIH awarding office. A copy of the summary statement is

automatically forwarded to the applicant as soon as possible.

The applicant will be notified by letter concerning the final review recommendation. Any questions about initial review recommendations and funding possibilities should be directed to the appropriate institute program official, not the scientific review administrator of the SRG. A Notice of Research Fellowship Award will be issued to applicants selected for funding.

E. Period of Support

All fellows are required to pursue their research training on a full-time basis, normally defined as 40 hours per week or as specified by the sponsoring institution in accordance with its own policies.

No individual fellow may receive more than five years of aggregate NRSA support at the predoctoral level and three years of aggregate NRSA support at the postdoctoral level, including any combination of NRSA support from institutional and individual awards. Any exception to this requires a waiver from the Director of the NIH awarding office or designee based on review of justification from the individual and sponsoring institution. The grounds for approving extensions of support are as follows:

1. Physicians/Clinicians

Individuals requiring additional time to complete training, either as a participant in a combined M.D.-Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training, may anticipate favorable consideration of a request for waiver of the time limitation. This action is contingent upon certification of the recipient's good academic standing and justified need for the exception to policy.

2. Interruptions (Break-In-Service)

Requests for additional time will also be considered if an event unavoidably has altered the planned course of the research training; the interruption has significantly detracted from the nature or quality of the planned research training; and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation, which prevents a trainee or fellow from pursuing research training in an effective manner for a significant period of time. Requests for extension of support will also be considered if a short additional period would provide the fellow an opportunity to use an exceptional training resource directly related to the approved research training program.

3. Other Exceptions

Requests that do not arise from circumstances considered in E.1 or E.2 above will be considered if they are accompanied by an exceptionally strong justification. Requests must be made in writing to the NIH awarding office by the fellow. The fellow's sponsor and an authorized institutional business official, must endorse the request certifying the need for additional support. The request must include a sound justification and specify the amount of additional support for which approval is sought. Requests must be approved by the Director of the awarding office or designee.

F. Initiation of Support

1. Process

The awarding office will notify the individual of the intention to make an award and confirm the actual plans for the start of the fellowship support. The Notice of Research Fellowship Award will be issued so that the individual may begin the fellowship immediately on or after the issue date, or permit a period of up to six months for the individual to finalize arrangements, such as the completion of degree requirements, final co-

ordination with the sponsor, and, if necessary, a move to the sponsoring institution. The fellow must start the period of training under the award by the latest activation date as shown on the Notice of Research Fellowship Award; i.e., six months from the award issue date. Extensions of the activation period may be granted in unusual circumstances. Written requests for extensions should be submitted by the fellow, and countersigned by the sponsor and authorized institutional business official.

The day the fellow begins training, the Activation Notice and the Payback Agreement (**only** for postdoctoral fellows in their first 12 months of NRSA postdoctoral support) must be completed and submitted to the awarding office (see Section H.1.a.(1) and (2)). A stipend may not be paid until these forms are submitted and the fellow begins training. If necessary for payroll purposes, the Activation Notice and Payback Agreement may be submitted up to 30 days in advance of the start date. However, any change in this planned activation start date must be reported immediately to the business office of the institution and the awarding office. If an award is conditioned upon the completion of degree requirements, certification of completion by the degree granting institution must be submitted with the Activation Notice.

The initial award is usually for 12 months. Subsequent periods of approved fellowship training are consecutive with the first year of support and are usually in 12-month increments. If a fellow decides not to activate the award, or to terminate early, he or she should notify the institutional business office, the sponsor, and the awarding office immediately in writing.

2. Payment

a. Domestic

(1) Domestic, Non-Federal

Sponsoring institutions receive an award for the stipend, institutional allowance, and tuition and fees (when applicable). The domestic institution directly pays the fellow and disburses all other awarded costs

(2) Federal Laboratories

Fellows training at Federal laboratories are paid stipends directly by the awarding office through the Office of Financial Management (OFM), which also reimburses the fellow for appropriate expenditures from the institutional allowance.

b. Foreign

Fellows training at foreign sites receive stipends directly from OFM; however, the institutional allowance is awarded to and disbursed by the sponsoring institution.

G. Financial Provisions

Costs are normally provided based on a 12-month budget period. Awards for less than 12 months will be prorated accordingly.

1. Stipends

A stipend is provided as a subsistence allowance for fellows to help defray living expenses during the research training experience. It is not provided as a condition of employment with either the Federal Government or the sponsoring institution. Stipends must be paid in accordance with stipend levels set by this policy. No departure from the standard stipend schedule, as provided from the fellowship, may be negotiated by the sponsoring institution with the fellow.

a. Levels

Stipend levels are published in the *NIH Guide for Grants and Contracts*. That publication should be reviewed for any changes to stipend levels.

(1) Predoctoral

One stipend level is used for all predoctoral candidates, regardless of the level of experience.

(2) Postdoctoral

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

(3) Senior Fellows

The amount of the NRSA stipend to be paid shall be commensurate with the base salary or remuneration which the individual receiving the award would have been paid by the institution with which he or she has permanent affiliation on the date of the fellowship award, but in no case shall the stipend award exceed the current NRSA stipend limit set by NIH. Fringe benefits are not provided with this award. The level of NRSA support will take into account concurrent salary support provided by the institution, and the policy of the sponsoring institution.

b. Stipend Supplementation

Fellows are supported for 12-month full-time training appointments for which they receive stipends to defray living expenses. Stipends may be supplemented by an institution from non-Federal funds provided this supplementation does not require any additional obligation from the fellow. An institution can determine what amount of stipend supplementation, if any, will be provided according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may PHS funds be used for supplementation.

An individual may make use of Federal educational loan funds or V.A. benefits when permitted by those programs as described in Section G.1.e. below.

c. Compensation

It is recognized that fellows may seek part-time employment coincidental to their training program in order to further offset their expenses. In circumstances of actual employment, the funds provided as compensation (salary or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation. Funds characterized as compensation may be paid to fellows when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions of the compensation of students as detailed in "Cost Considerations—Allowability of Costs/ Activities—Selected Items of Cost—Salaries and Wages—Compensation of Students" in Part II of this policy statement. Under these conditions, fellows may be compensated for actual employment on Federal grants, including PHS research grants. However, it is expected that compensation from research grants will occur on a limited part-time basis for employment apart from the normal training activities.

Compensation may not be paid from a research grant which supports the same research that is part of the fellow's planned training experience as approved in the fellowship application. Fellowship sponsors must approve all instances of employment on research grants in order to verify that the circumstances will not detract from or prolong the approved training program.

Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved NRSA training program. Additionally, compensation must be in accordance with institutional policies applied consistently to both federally and non-federally supported activities and supported by acceptable

accounting records determined by the employer-employee relationship agreement.

d. Concurrent Benefits

A National Research Service Award may not be held concurrently with another federally sponsored fellowship or similar Federal award which provides a stipend or otherwise duplicates provisions of the NRSA.

e. Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the Department of Veterans Affairs (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation.

f. Taxability of Stipends

Section 117 of the Internal Revenue Code applies to the tax treatment of scholarships and fellowships. The Tax Reform Act of 1986, Public Law 99-514, impacts on the tax liability of all individuals supported under the NRSA program. New statutory requirements were effective as of January 1, 1987. Degree candidates may now exclude from gross income (for tax purposes) any amount used for course tuition and related expenses such as fees, books, supplies and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are now required to report as gross income all stipends and any monies paid on their behalf for course tuition and fees required for attendance.

The taxability of stipends, however, in no way alters the relationship between NRSA fellows and sponsoring institutions. NRSA stipends are not considered salaries. In addition, fellows supported under the NRSA are not considered to be in an employee-employer relationship with the NIH or the sponsoring institution.

It must be emphasized that the interpretation and implementation of the tax laws are the domain of the Internal Revenue Service and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

g. Form 1099

Since stipends are not considered salaries, for the purposes of income tax reporting, stipend payments should be reported on the IRS Form 1099, Statement of Miscellaneous Income. The business office of the sponsoring institution will be responsible for the annual preparation and issuance of the IRS Form 1099 for fellows paid through the institution. NIH will issue the subject form for all fellows paid directly by them (e.g., fellows training at Federal or foreign laboratories).

h. Employee Benefits

Since NRSA awards are not provided as a condition of employment with either the Federal government or the sponsoring institution, it is inappropriate and unallowable for institutions to seek funds for or to charge individual fellowship awards for costs that would normally be associated with employee benefits (for example, FICA, workman's compensation, and unemployment insurance).

2. Other Costs

a. Institutional Allowance

An institutional allowance to help support the costs of training is awarded. Interested applicants should consult the NIH program announcement(s) regarding the specific level of allowance for predoctoral and postdoctoral support, including those individuals training at Federal laboratories, for-profit, or foreign institutions. Allowance levels are published in the *NIH Guide for Grants and Contracts*. Current institutional allowance levels are found in Appendix 1. Beginning in FY 1997, for postdoctoral fellowships, costs for tuition and fees, where appropriate, will

be awarded independent from the institutional allowance. (See Section 2.b for details on tuition reimbursement.)

(1) Allowable Costs for Sponsoring Institutions

The type of sponsoring institution dictates what allowable costs may be charged to this category and how the funds are administered.

(a) Non-Federal public and private non-profit institutions

The allowance is intended to defray such expenses for the individual fellow as research supplies, equipment, travel to scientific meetings, health insurance and to otherwise offset, insofar as possible, appropriate administrative costs of graduate training. Funds are paid directly to and administered by the sponsoring institution.

(b) Federal laboratories

The allowance is intended to cover the costs of scientific meeting travel, health insurance, or books. Funds are administered by the awarding office and disbursed from OFM.

(c) For-profit institutions

The allowance is intended to cover the costs of scientific meeting travel, health insurance, or books. Funds are paid directly to and administered by the sponsoring institution.

(d) Foreign institutions

The allowance is intended to defray such expenses as research supplies, equipment, travel to scientific meetings, health insurance and to otherwise offset, insofar as possible, appropriate administrative costs of graduate training. Funds are paid directly to and administered by the sponsoring institution.

(2) Guidelines

The following are specific guidelines for the use of the institutional allowance:

(a) Health Insurance:

A fellow's health insurance is an allowable cost only if required of all persons in a similar training status regardless of the source of support. Family health insurance is not an appropriate charge; however, the individual may elect personally to pay the differential between self-only and family health insurance options.

(b) Travel

1) Payment for travel to scientific meetings is appropriate when it is necessary to the individual's training. 2) For fellows at Federal laboratories, reimbursement of travel costs is in accordance with current Government regulations. 3) Funds may not be expended to cover the costs of travel between the fellow's place of residence and the domestic training institution, except that the grantee institution may authorize the cost of a one-way travel allowance in an individual case of extreme hardship.

(c) Extraordinary Costs

Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for: 1) travel to field sites remote from the sponsoring institution; or 2) accommodations for fellows who are disabled, as defined by the Americans With Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances which are fully justified and explained by the institution.

(3) Expenditure

Except for fellows at Federal training sites, the sponsoring institution authorizes the expenditure of the allowance on behalf of the fellow according to the institutional policy. The institution is entitled to expend up to the full institutional allowance upon official activation of the award. However, if an individual fellow is not in a

training status for more than six months of the award year, only one-half of that year's allowance may be charged to the grant. The Notice of Research Fellowship Award will be revised and the balance must be refunded to NIH.

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

b. Tuition and Fees

Tuition and fees for postdoctoral fellows are limited to those for specific courses required by the training program and must receive prior approval from the awarding office. For the purposes of calculating this budget item, health insurance is not included since it is still awarded as part of the institutional allowance

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

Reimbursement of tuition and fees changed with awards competing in FY97. See Appendix 1 for details.

c. Travel to Foreign Training Sites

For fellows at foreign training sites, in addition to the institutional allowance, awards may include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement shall not be influenced by factors of cost, convenience, or personal travel preference.

H. Reporting Procedures

The following documents are critical to the process of establishing the payment of stipends and other costs, as well as the determination of possible payback service.

1. Activation Notice

Immediately upon the initiation of training, the individual completes and signs the Activation Notice (Form PHS 416-5), obtains the signature of the designated sponsoring institution officials, and forwards the notice along with the Payback Agreement (postdoctoral fellows in their first 12 months of NRSA support only) to the NIH awarding office. An Activation Notice is enclosed with all competing awards.

For fellows paid directly by NIH, the Activation Notice is required at the start of each award year. The forms should not be submitted before he or she actually begins training. Stipend checks are issued when both the Activation Notice and the Payback Agreement (postdoctoral fellows in their first 12 months of NRSA support only) are received by the awarding office.

For fellows whose stipend is paid through the institution, the Activation Notice is required for the initial year only. The Notice may be submitted up to 30 days before the individual begins training if necessary for payroll purposes. However, the institution must not release any funds until the individual has actually started training. Furthermore, if the individual does not begin research training on the day indicated, the institution must notify the NIH awarding office immediately. Continuation awards must be activated on the day following termination of the previous award period.

2. Payback Agreement

A National Research Service Award Payback Agreement (Form PHS 6031) must be signed by each person who is to receive an individual postdoctoral fellowship that covers their initial 12 months of NRSA postdoctoral support. If the individual has already received 12 months of postdoctoral NRSA support under any grant or award, this form is not required. For detail on NRSA payback, see Section IV.

3. Termination Notice

The Termination Notice (Form PHS 416-7)(along with the Activation Notice and the Notice of Research Fellowship Award) is the basis for establishing the amount of payback obligation for each NRSA fellow. For individual fellowships, a Termination Notice is sent to the fellow by the awarding office prior to the scheduled termination date. For early terminations, the forms will be issued immediately upon receipt of notification from the fellow or an authorized institutional official. This form must be completed and returned to the awarding office immediately. The lack of timely and accurate information on this form could adversely affect the payback process.

4. Consecutive Support

If a fellow switches from one NRSA grant mechanism to another, including from one awarding office to another, the requirement for payback service incurred is deferred until the total NRSA support is completed. All fellowship applications are reviewed to determine if previous NRSA support has been provided.

I. Progress Reports, Financial Status Reports, Changes in the Project

1. Progress Reports

Progress reports must be submitted with all applications for non-competing continuation support in accordance with the instructions accompanying the application forms. Inadequate or incomplete progress reports may be returned to the fellow for revision and may result in a delay of continued support. For individual awards the final progress report is required as part of the Termination Notice.

2. Financial Status Report

An annual or final Financial Status Report is not required on individual awards. In the event of early termination, the stipend will be prorated according to the amount of time spent in training and the Notice of Research Fellowship Award will be revised. The balance of any institutional allowance (at least 1/2) must be refunded if the training has been for six months or less.

3. Changes in the Project

Individual awards are made for training at a specific institution under the guidance of a particular sponsor. A transfer of the award to another institution or a change in sponsor and/or project requires the approval of the NIH awarding office. As part of that approval process, if a fellow sponsored by a domestic non-Federal institution requests a transfer to another domestic non-Federal institution before the end of the current award year, the initial institution may be requested to continue to pay the stipend until the end of the current year. Disposition of the institutional allowance is negotiable between the two sponsoring institutions.

Transfers involving Federal or foreign sponsoring institutions require unique administrative procedures and approvals. Regardless of the type of sponsoring institution involved, since each transfer varies depending upon individual circumstances, the NIH awarding office should be contacted for specific guidance.

Any proposed change in the individual's specified area of research training must be reviewed and approved in writing by the awarding office to assure that the training continues to be an area that falls within the scientific area of the original peer reviewed application.

An interim sponsor must be named by the institution and approved in writing by the awarding office when the sponsor is going to be absent for a period of more than three months.

J. Other Terms and Conditions

1. Leave

a. Vacations and Holidays

Fellows may receive the same vacations and holidays available to individuals in comparable training positions at the grantee or sponsoring institution. Fellows shall continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters is generally considered an active part of the training period.

b. Sick Leave and Other Leave

Fellows may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the awarding office in response to a written request from the sponsor, countersigned by an authorized institutional official. Sick leave may be used for the medical conditions related to pregnancy and childbirth.

c. Parental Leave

Fellows may also receive stipends for up to 30 calendar days of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee or sponsoring institution have access to paid leave for this purpose. Either parent is eligible for parental leave. In the case of individual fellowships, the use of parental leave requires approval by the sponsor.

A period of terminal leave is not permitted and payment may not be made from grant funds for leave not taken.

d. Unpaid Leave

Individuals requiring extended periods of time away from their research training experience, which could include more than 15 calendar days of sick leave or more than 30 calendar days of parental leave must seek approval for an unpaid leave of absence. Approval for a leave of absence must be requested in advance from the awarding office. Fellows must provide a letter of support from the sponsor, countersigned by an authorized institutional official, and must advise the awarding office of the dates of the leave of absence. Upon approval of the request, the awarding office will issue a revised Notice of Research Fellowship Award extending the termination date of the current budget period by the number of months of the leave. A restriction will be included in the terms and conditions of the award precluding the expenditure of funds from the fellowship during the period of the leave of absence.

During a leave of absence, documentation to suspend the award and/or the accrual of service for calculating the payback obligation must be completed.

2. Termination

An individual award may be terminated prior to its normal expiration date at the written request of the recipient, or by the Director, NIH, if it is found that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. In the event an award is terminated for cause, the Director, NIH, shall notify the awardee in writing of this determination, the reasons therefore, the effective date, and the right to appeal the decision.

3. Publications

Fellows are encouraged to submit reports of their findings for publication to the journals of their choice. Responsibility for direction of the project should not be ascribed to NIH. Awarding office support must be acknowledged by a footnote in language similar to the following: "This Investigation was supported by National Institutes of Health, National Research Service Award (number) from the (awarding office)." In addition, it is now mandated that all grantees funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. 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.

4. Copyright

Except as otherwise provided in the conditions of the award, when publications or similar copyrightable materials are developed from work supported by NIH the author is free to arrange for copyright without awarding office approval. Any such copyrighted material shall be subject to royalty-free, nonexclusive, and irrevocable license to the Government to reproduce them, translate them, publish them, use and dispose of them, and to authorize others to do so for Government purposes.

5. Patents

No fellowship grant made by NIH primarily to an awardee for educational purposes for training other than at NIH will contain any provision giving NIH any rights to inventions made by the awardee. Fellows training at NIH are bound by all provisions of Executive Order 10096 and any orders, rules, regulations or issuances thereunder wherein NIH determines the rights of the Government and the fellow in (and to) inventions conceived or actually reduced to practice during the period of fellowship.

6. Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award may not be retained by the fellow. Such fees will be assigned to the sponsoring institution for disposition in accordance with NIH policy on grant-related (program) income (see "Administrative Requirements—Management Systems and Procedures—Program Income" in Part II of this policy statement). The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations. These fees, if within institutional policy, may be retained by the awardee.

7. Human Subjects/Animal Welfare/ Recombinant DNA

a. Human Subjects

The HHS regulations for the protection of human subjects 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 HHS. The regulations stipulate that the sponsoring institution, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in HHS-supported research activities. The regulations require that the sponsoring institution file a written Assurance of Compliance with the Office for Protection from Research Risks (OPRR). If a project involves nonexempt human subjects research, certification that an appropriate Institutional Review board has reviewed and approved the proposed activity is also required.

For additional information on human subjects requirements, please refer to the Individual NRSA application kit or contact the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Blvd., Suite 3B01, Mail Stop Code 7507, Bethesda, MD 20892-7507, Telephone: (301) 496-7041.

b. Vertebrate Animals

The *PHS Policy on Humane Care and Use of Laboratory Animals* requires that sponsoring institutions (foreign or domestic) proposing to use vertebrate animals file a written Animal Welfare Assurance with the OPRR, establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by NIH. Verification of the date the Institutional Animal Care and Use Committee approved the project is also required.

For additional information on vertebrate animals, please refer to the Individual NRSA application kit or contact the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Blvd., Suite 3B01, Mail Stop Code 7501, Bethesda, MD 20892-7507, Telephone: (301) 496-7163.

c. Recombinant DNA

The current *NIH Guidelines for Research Involving Recombinant DNA Molecules* and announcements of modifications and changes to the Guidelines are available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, MD 20892. All research involving recombinant DNA techniques that is supported by HHS must meet the requirements of these Guidelines.

III. Institutional National Research Service Awards (Training Grants)

A. General

The National Institutes of Health (NIH) will award National Research Service Award (NRSA) Institutional Training Grants (T32s, T34s, & T35s) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the institution, who are training for careers in specified areas of biomedical and behavioral research. The purpose of the NRSA program is to help ensure that highly trained scientists are available in adequate numbers and in the appropriate research areas and fields to carry out the Nation's biomedical and behavioral research agenda. The NRSA program supports both predoctoral and postdoctoral research training as well as limited specialized support at the prebaccalaureate level. Note, all NIH awarding offices except the Fogarty International Center (FIC) and the National Library of Medicine (NLM) make institutional awards under NRSA. FIC & NLM have unique funding authorities for training grants that are not under the NRSA.

1. Eligibility

a. Applicant Eligibility

A domestic, non-profit public or private institution may apply for a grant to support a research training program in a specified area(s) of research. Support for predoctoral, postdoctoral, or a combination of trainees may be requested. (Specific program announcements should be referred to for awarding office guidelines.) Support for short-term training positions for students in health-professional degree programs may also be requested as indicated under 2.c. below. Each applicant institution must submit an application according to instructions, using the appropriate forms (see Section B).

b. Research Areas

National Research Service Awards may be made for research training in areas which fall within the mission of the NIH ICs. Applications which do not fit these areas will be returned. An increased emphasis has been placed on the research training of physicians. The Secretary, DHHS is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of two consecutive years of biomedical and behavioral research training.

The applicant institution must have a strong research program in the area(s) proposed for research training and must have the requisite staff and facilities required to carry out the proposed program. The research training program director at the grantee institution will be responsible for the selection and appointment of trainees and the overall direction of the training program. In selecting trainees, the program director must make certain that individuals receiving support meet the eligibility requirements set forth in these guidelines.

Trainees appointed to the training program must have the opportunity to carry out supervised biomedical or behavioral research with the pri-

mary objective of developing or extending their research skills and knowledge in preparation for a research career.

c. Research Training Program

The National Research Service Award must be used to support a program of research training. The NRSA may not support studies leading to the M.D., D.O., D.D.S., D.V.M., or other clinical, health professional degrees; nor to support residencies, the primary purpose of which is the attainment of a medical or nursing specialty. Research trainees in clinical areas are expected to devote full time to the proposed research training. During the 40 hours per week required for research training, any clinical duties should be confined to those which are part of the research training.

2. Degree Requirements

a. Predoctoral Training

Predoctoral research training is for individuals who have a baccalaureate degree and are enrolled in a doctoral program leading to the either the Ph.D. degree, a comparable research doctoral degree, or the combined M.D./Ph.D. Students enrolled in health-professional programs that are not part of a formal, combined program (i.e., M.D./Ph.D.) and who wish to postpone their professional studies in order to gain research experience, may also be appointed to a T32 grant. Predoctoral research training must emphasize fundamental training in areas of basic biomedical and behavioral sciences.

b. Postdoctoral Training

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

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

c. Short-Term Research Training

Students in Health Professional Schools. NIH offers two short-term training programs; those which are part of a traditional institutional training grant (T32) and those which exclusively support short-term trainees (T35). These short-term research training experiences of two to three months are available to students in health professional schools. All short-term training must be full-time. Unless otherwise stated, provisions for institutional training grants apply. Current stipend levels are published in the *NIH Guide for Grants and Contracts*.

(1) T32 T32 applications may include a request for short-term positions reserved specifically to train medical or other health-professional students on a full-time basis during the summer or other "off-quarter" periods. Short-term appointments are intended to provide health-professional students with opportunities to participate in biomedical and/or behavioral research in an effort to attract these individuals into research careers.

To be eligible for short-term research training positions, health-professional students must have completed at least one quarter at an accredited health-professional school leading to a clinical doctorate prior to participating in the program. Trainees need not be enrolled at the applicant institution. Individuals matriculated in a formal research degree program, or those holding an M.S., a Ph.D., an M.D./Ph.D. or an equivalent graduate level research degree are not eligible.

Within schools of pharmacy, only individuals who are candidates for the Pharm. D. degree are eligible.

Short-term positions should be longer than 2 months but may not last longer than 3 months. Students should be encouraged to obtain two or more periods of short-term research training during their studies leading to a health-professional degree. Such appointments may be consecutive or may be reserved for summers or other "off-quarter" periods.

Since some NIH Institutes support short-term research training positions on a limited basis, applicants are strongly urged to contact the appropriate NIH awarding office before requesting short-term research training positions as part of a T32 application.

(2) T35 Several NIH awarding offices provide short-term research using a separate training grant mechanism (T35). The program intent and student eligibility requirements are similar to those indicated above. However, since this NRSA funding mechanism is used by only a few NIH awarding offices, interested applicants are encouraged to contact specific awarding offices for details.

d. Prebaccalaureate Training

Under the auspices of the institutional undergraduate NRSA (T34), two distinct programs for prebaccalaureate training are offered. Both programs are designed to support students from institutions with a substantial minority enrollment.

(1) The National Institute of General Medical Sciences (NIGMS) administers The MARC Undergraduate Student Training and Research (U*STAR) program. Formerly know as Honors Undergraduate Research Training Program (HURT), this training program is designed to support selected junior/senior undergraduate honors students at baccalaureate colleges and universities.

NIGMS recognizes that because of the heterogeneity at minority institutions there are differences in institutional missions. Therefore, the emphasis of this program will be on the specific objectives and measurable goals which the applicant institution sets for itself as being achievable. For more information on this program, contact:

MARC Program, NIGMS
Room 2AS.37D
45 Center Drive MSC 6200
Bethesda, MD 20892-6200
Phone: (301) 594-3900,
Fax: (301) 480-2753

(2) The National Institute of Mental Health (NIMH) administers The Career Opportunities in Research (COR) Education and Training Program. The intent of this program is to strengthen research and research training experiences in scientific disciplines related to mental health. An applicant institution (a four-year college or university) must propose a two-year COR Honors Undergraduate Program for which six to ten highly talented third and fourth-year undergraduate students will be selected. Students will be provided with special research training experiences designed to improve their qualifications for entry into advanced research training programs leading to the doctoral-level or M.D. research career degrees. For more information on this program contact:

COR Program
Office of Special Populations/NIMH
Parklawn Building, Room 17C14
Rockville, MD 20852
(301) 443-2847

3. Citizenship

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 appointment. A non-citizen national is a person, who, although not a citizen of the United States, owes permanent allegiance to the U. S. They are generally persons born in outlying possessions of the United States (e.g.; American

Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must be in possession of a currently valid Alien Registration Receipt Card (I-551), or must be in possession of other legal verification of such status. For example, if an individual is in possession of the proper validation on their passport, a notarized photocopy of the passport could suffice. Since there is a six-month limitation on this validation, it is the responsibility of the grantee institution to follow-up and assure that the individual received the I-551 prior to the six month expiration date.

A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment Form (PHS Form 2271). Individuals on temporary or student visas are not eligible for support from the NRSA.

B. Applications and Receipt Dates

1. Application

The application for the institutional training grant is Form PHS 398. It contains special instructions for Institutional National Research Service Awards. Application kits containing forms, instructions, and related information may be obtained from:

The Division of Extramural Outreach and
Information Resources, OER, NIH
6701 Rockledge Drive, MSC 7910
Bethesda, MD 20892-7910
Phone: (301)-435-0714
E-mail: grantsinfo@ od.nih.gov

2. Receipt Dates

Many of the NIH awarding offices receive training grant applications three times each year. Some awarding offices have only one or two receipt date(s). Information on receipt dates is available in the NIH-wide T32 Information Statement or in RFAs issued by the individual awarding offices. See Appendix 2 for a complete listing of the current receipt dates and review cycle.

Applicants are encouraged to contact appropriate NIH staff before preparing and submitting an application.

C. Review

1. Overall

Each initial and competing continuation application will be evaluated for scientific merit by a NIH peer review group. Institutional applications must also be reviewed by the appropriate Council or Board of the IC whose activities relate to the proposed research training.

Institutional applications will be evaluated using criteria such as: a) past research training record of both the program and the designated preceptors; b) objectives, design, and direction of the research training program; c) caliber of preceptors as researchers including successful competition for research support; d) recruitment and selection plans for trainees and the availability of high quality candidates; and e) the institutional training environment including the level of institutional commitment, quality of the facilities, availability of appropriate courses, and the availability of research support.

In addition, where appropriate, the record of the research training program in retaining health-professional postdoctoral trainees for at least two years in research training or other research activities; and the concomitant training of health-professional postdoctorates (e.g., individuals with the M.D., D.O., D.D.S.) with basic science postdoctorates (e.g., individuals with a Ph.D., Sc.D.) or linkages with basic science departments will receive special consideration.

While overall criteria are described above, applicants are encouraged to consult the PHS 398 application kit, the NIH T32 program announcement and/or specific awarding office program announcements for specific details.

2. Short-Term Research Training Positions

In addition to the overall program criteria described above, applications that request short-term research training positions in conjunction with full-time positions will also be assessed using specific criteria. The NIH T32 program announcement and/or specific awarding office program announcements should be consulted for details.

3. Minority Recruitment Plan

The NRSA institutional training grant program must provide for the recruitment and retention of individuals from underrepresented minority groups including, but not limited to, African Americans, Hispanic Americans, Native Americans, Alaskan Natives and Pacific Islanders. All competing applications for institutional NRSA research training grants must include a specific plan to recruit minorities, and competing continuation applications also must include a report on the recruitment and retention record during the previous award period. If an application is received without a plan, or without a report on the previous award period, the application will be considered incomplete and may be returned to the applicant without review. Additional information on this requirement is available in the NIH T32 Program Announcement.

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

- Students and/or postdoctorates in the department(s) relevant to the training grant;
- Individuals who applied for research training;
- Individuals who were offered admission; and
- Individuals who were appointed to the research training grant.

For those trainees who were appointed to the grant, the report should include information about the duration of research training and whether those trainees have finished their training in good standing.

Peer reviewers will examine and evaluate the minority recruitment plan and any record of recruitment and retention after the overall educational and technical merit of an application has been assessed so that the quality of the plan will not be a factor in determining the priority score. For competing continuation applications, the reviewers will examine and evaluate the record of the program in recruiting and retaining underrepresented minority trainees during the previous award period. The panel also will consider whether the experience in recruitment during the previous award period has been incorporated into the formulation of the recruitment plan for the next award period.

The findings of the panel will be included in an administrative note in the summary statement. If the minority recruitment plan of the application is judged to be unacceptable, funding will be withheld until a revised plan that addresses the deficiencies is received. Staff within the NIH awarding office, with guidance from the appropriate national advisory committee or council, will determine whether amended plans and reports submitted after the initial review are acceptable.

Information on the recruitment and retention of underrepresented minority trainees appointed during the previous period must also be provided in progress reports included in all non-competing applications.

4. Training in the Responsible Conduct of Research Training

All competing NRSA institutional training grant applications must include a description of the formal and informal activities related to

instruction on the responsible conduct of research that will be incorporated into the proposed research training program.

Every prebaccalaureate, pre and postdoctoral NRSA trainee must receive instruction on the responsible conduct of research. Applications must include a description of a program to provide formal or informal instruction in scientific integrity and/or the responsible conduct of research, as follows:

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

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

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

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

NIH encourages institutions to provide instruction in the responsible conduct of research to all individuals in a training program or department, regardless of the source of support.

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

Following initial review, applications undergo a second level review by the appropriate NIH institute or center council, board, or other advisory group. These advisory groups will consider, in addition to the assessment of the scientific and educational merit of the research training grant application, the initial review group's comments on the recruitment of individuals from underrepresented minority groups into the research training program and the plan for instruction in the responsible conduct of research.

Information on the nature of the instructions in the responsible conduct of science and the extent of trainee and faculty participation must also be provided in progress reports included in all noncompeting applications.

D. Notification of Action

Shortly after the initial review meeting, each applicant will be sent a mailer that includes the SRG recommendation/priority score and the name of a program official in the assigned NIH awarding office. The awarding office automatically forwards a copy of the summary statement to the applicant as soon as possible after receipt from the SRG. The applicant will be notified by letter concerning the final review recommenda-

tion. A Notice of Grant Award will be issued to applicants selected for funding. Any questions about initial review recommendations and funding possibilities should be directed to the appropriate awarding office program official, not the scientific review administrator of the SRG.

E. Period of Support

1. Institutional Grants

Grants may be made for competitive segments of up to five years and are renewable. Awards within an approved competitive segment are normally made in 12-month increments with support for additional non-competitive years dependent upon satisfactory progress and availability of funds.

2. Trainees

Trainees are customarily appointed for full-time 12-month continuous periods. An appointment or reappointment may not exceed 12 months without prior approval by the NIH awarding office. All trainees are required to pursue their research training on a full-time basis, normally defined as 40 hours per week or as specified by the grantee institution in accordance with its own policies. The amount of the stipend, tuition and fees for each full period of appointment must be obligated from funds available at the time the individual begins training unless other instructions are furnished by the awarding office.

With the exception of specifically designated short-term research training positions, no trainee may be appointed under a regular institutional grant for a period of less than nine months except with the prior written approval of the awarding office and then usually only to complete a planned program of training. An initial appointment of less than nine months may be allowed as long as an assurance is included that the individual will be immediately reappointed in the subsequent year so that the cumulative continuous training period is at least nine months.

3. NRSA Limitations

No individual trainee may receive more than five years of aggregate NRSA support at the predoctoral level and three years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional and individual awards. Any exception to this requires a waiver from the Director of the awarding office or designee based on review of justification from the individual and grantee institution. The grounds for approving extensions of support are as follows:

a. Physicians/Clinicians

Individuals requiring additional time to complete training, either as a participant in a combined M.D.-Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training, may anticipate favorable consideration of a request for waiver of the time limitation. This action is contingent upon certification of the recipient's good academic standing and justified need for the exception to policy.

b. Interruptions (Break-in-Service)

Requests for additional time will also be considered if an event unavoidably has altered the planned course of the research training; the interruption has significantly detracted from the nature or quality of the planned research training; and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation which prevents a trainee from pursuing research training in an effective manner for a significant period of time. Requests for extension of support will also be considered if a short additional period would provide the trainee an opportunity to use an exceptional training resource directly related to the approved research training program.

c. Other Exceptions

Requests that do not arise from circumstances considered in 3.a or 3.b above will be considered if they are accompanied by an exceptionally strong justification. Requests must be made in writing to the NIH awarding office by the trainee. The trainee's program director and an authorized institutional official, must endorse the request certifying the need for additional support. The request must include a sound justification and specify the amount of additional support for which approval is sought. Requests must be approved by the Director of the awarding office or designee.

F. Initiation of Support

A Notice of Grant Award is issued to the grantee institution, normally with a budget period of 12 months. A predoctoral or postdoctoral trainee may be appointed at any time during the course of the budget period for an appointment period of 9 to 12 months, without prior approval by the awarding office.

At the time of the initial appointment and subsequent reappointments, the training program director **must** submit a Statement of Appointment Form to the awarding office. Additionally, a signed Payback Agreement must be submitted for each postdoctoral trainee who is in his/her first 12 months of NRSA postdoctoral support. (See Sections H.1. and 2 for specific information on required forms). The Statement of Appointment Form includes biographical data on the trainee and the stipend level for the period of appointment. The stipend is paid by the grantee institution directly to the trainee.

G. Financial Provisions

1. Stipends

A stipend is provided as a subsistence allowance for trainees and fellows to help defray living expenses during the research training experience. It is not provided as a condition of employment with either the Federal Government or the grantee institution. Stipends must be paid in accordance with established stipend levels. No departure from the standard stipend schedule, as provided from the grant, may be negotiated by the grantee institution with the trainee. For appointments of less than 12 months, the stipend will be prorated.

a. Levels

Stipend levels are published in the *NIH Guide for Grants and Contracts*. That publication should be reviewed for any changes to stipend levels.

(1) Prebaccalaureate

Two separate levels are provided for trainees: Freshman/Sophomore or Junior/Senior.

(2) Predoctoral

One stipend level is used for all predoctoral individuals regardless of the level of experience.

(3) Postdoctoral

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

b. Stipend Supplementation

Trainees are supported for 12-month full-time training appointments for which they receive stipends to defray living expenses. Stipends may be supplemented by an institution from non-Federal funds provided this supplementation is without obligation to the trainee. An institution can determine what amount of stipend supplementation, if any, will be provided according to its own for-

mally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar training status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. An individual may make use of Federal educational loan funds or V.A. benefits when permitted by those programs as described below in paragraphs G.1.d and e. Under no circumstances may PHS funds be used for supplementation.

c. Student Compensation

It is recognized that trainees as students may seek part-time employment coincidental to their training program in order to further offset their expenses. In circumstances of actual employment, the funds provided as compensation (salary or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation. Funds characterized as compensation may be paid to trainees when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions of the compensation of students as detailed in "Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages—Compensation of Students" in Part II of this policy statement. Under these conditions trainees may be compensated for actual employment on Federal grants, including PHS research grants. However, it is expected that compensation from research grants will occur on a limited part-time basis for employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant which supports the same research that is part of the trainee's planned training experience as approved in the training grant application. Institutional training grant program directors must approve all instances of employment on research grants in order to verify that the circumstances will not detract from or prolong the approved training program.

Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the trainee's approved NRSA training program. Additionally, compensation must be in accordance with institutional policies applied consistently to both federally and non-federally supported activities and supported by acceptable accounting records determined by the employer-employee relationship agreement.

d. Concurrent Benefits

A National Research Service Award may not be held concurrently with another Federally-sponsored fellowship or similar Federal award which provides a stipend or otherwise duplicates provisions of the NRSA.

e. Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the Department of Veterans Affairs (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation. In the case of the MARC-USTAR program, funds from a PELL grant may be accepted as well.

f. Taxability of Stipends

Section 117 of the Internal Revenue Code applies to the tax treatment of scholarships and fellowships. The Tax Reform Act of 1986, Public Law 99-514, impacts on the tax liability of all individuals supported under the NRSA program. New statutory requirements were effective as of January 1, 1987. Degree candidates may now exclude from gross income (for tax purposes) any amount used for course tuition and related expenses such as fees, books, supplies and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are now required to report as gross income all stipends and any monies paid on their behalf for course tuition and fees required for attendance.

The taxability of stipends, however, in no way alters the relationship between NRSA trainees and institutions. NRSA stipends are not considered salaries. In addition, trainees supported under the NRSA are not considered to be in an employee-employer relationship with the NIH or the grantee institution.

It must be emphasized that the interpretation and implementation of the tax laws are the domain of the Internal Revenue Service and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

g. Form 1099

Since stipends are not considered salaries, for the purposes of income tax reporting, stipend payments should be reported on the IRS Form 1099, Statement of Miscellaneous Income. The business office of the grantee institution will be responsible for the annual preparation and issuance of the IRS Form 1099 for trainees.

h. Employee Benefits

Since NRSA awards are not provided as a condition of employment with either the Federal government or the grantee institution, it is inappropriate and unallowable for institutions to seek funds for or to charge institutional training grants awards for costs that would normally be associated with employee benefits (for example, FICA, workman's compensation, and unemployment insurance).

2. Other Direct Costs

a. Training-Related Expenses

Funds are provided to defray such training costs as staff salaries, consultant costs, equipment, research supplies, staff travel, and other expenses directly related to the training program. Funds are requested and awarded as a lump sum on the basis of the predetermined amount per predoctoral and postdoctoral trainee approved for support. Levels are published in the *NIH Guide for Grants and Contracts*. Current levels are found in Appendix 1. Interested applicants should be advised to consult the program announcement regarding the specific level for programs such as the short-term training program, the MARC program, or the COR program.

Under exceptional circumstances, which can include accommodating the disabilities of a trainee, it is possible to request institutional costs above the standard rate. Requests for additional costs must be explained in detail and carefully justified in the application. Consultation with NIH program staff in advance of such requests is strongly advised.

b. Trainee Tuition and Fees

Tuition, fees, and health insurance are allowable trainee costs only if such charges are required of all persons in a similar training status at the institution, without regard to their source of support. Family health insurance is not an appropriate charge. However, the trainee may elect personally to pay the differential between self and family health insurance options. Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program and requires prior approval of the awarding office. For the purposes of award, tuition, fees and health insurance are awarded together in a single budget category. Funds are awarded based on a formula applied to the requested level. The formula is described in Appendix 1.

c. Trainee Travel Costs

If requested by the institution, the awarding office may award grant funds to cover the costs of trainee travel including attendance at scientific meetings which the institution determines to be necessary to the individual's training. Funds may not be expended to cover the costs of travel between the trainee's place of residence and the training institution, except that the grantee insti-

tution may authorize a one-way travel allowance in an individual case of extreme hardship.

In addition, support for travel to a research training experience away from the grantee institution may be permitted. Research training experiences away from the parent institution must be justified considering the type of opportunities for training available, how these opportunities differ from those offered at the parent institution, and the relationship of the proposed experience to the trainee's career stage and career goals. This type of research training requires prior approval from the awarding office. Letters requesting such training may be submitted to the awarding office at any time during the award period.

d. Short-term

The institution may receive up to $125 per month to offset the costs of tuition, fees, travel, supplies, and other expenses for each short-term, health-professional research training position.

3. Rebudgeting of Funds

a. Trainee-Related Expenses

Expenditure and rebudgeting of funds awarded in lump sum for trainee-related expenses do not require awarding office prior approval.

b. Trainee Costs

For the purposes of rebudgeting, trainee costs include stipends and tuition and fees (including health insurance). These costs may not be used for other purposes except under unusual circumstances and then only with the prior written approval of the awarding office. Rebudgeting into or within the stipends and tuition/fees categories is allowable without awarding office prior approval.

c. Trainee Travel

For the purposes of rebudgeting, trainee travel is not considered a trainee cost and, therefore, may be rebudgeted into any other budget category without prior approval.

4. Expenditure of Funds

Policies governing expenditure of all training grant funds are those permitted under the applicable cost principles and this policy statement, unless otherwise indicated in the Notice of Grant Award.

5. Facilities and Administrative (F&A) Costs

The institution will receive F&A costs (previously "indirect costs") based solely on 8% of total direct costs exclusive of tuition and fees and health insurance, and expenditures for equipment. Applications from State and local government agencies, except State universities or hospitals, may receive full F&A cost reimbursement.

6. Program Income

Policy requires applicants for NIH research grants, including training grants, to include in their grant applications an estimate of the amount and source of program income expected to be generated as a result of the project for which support is being sought. See "Administrative Requirements—Management Systems and Procedures—Program Income" in Part II of this policy statement for policies that govern the treatment of program income.

H. Reporting Procedures

The following documents are critical to the process of establishing the payment of stipends and other costs, as well as the determination of possible payback service. Failure to submit the required forms in a timely manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

1. Statement of Appointment (Form PHS 2271)

a. Grantee Submission

The institution must submit this form to the NIH awarding office prior to or at the start of each trainee's appointment or reappointment. **No stipend or other allowance may be paid until the**

appointment form has been submitted. If the support covers the individual's initial 12 months of postdoctoral support, a signed Payback Agreement must also be submitted. It is important to note that the information on the Statement of Appointment and the Termination Notice is the basis for determination of the length or amount of an individual's payback requirement. An accurate social security number should be included on the Statement of Appointment and all other documents. The program director and the institutional financial officials should coordinate the information reported on the Statement of Appointment. It should be treated as a financial document for obligating costs (stipends) which later are reflected on the Termination Notice and as part of the total costs in the Financial Status Report. A supply of Statement of Appointment Forms (PHS 2271) is provided to the program director by the awarding office. In FY96, NIH began piloting the electronic receipt of the information on the PHS 2271. A number of grantee institutions are currently testing this system.

b. Interim Revisions

Any changes or corrections involving a trainee appointment under an institutional grant, such as, name, permanent mailing address, period of training, stipend support, must be reported by the training program director to the awarding office on an amended PHS-2271 at the time of the change.

2. Payback Agreement (Form PHS 6031)

A National Research Service Award Payback Agreement must be signed by each postdoctoral individual for whom the appointment covers his/her initial 12 months of postdoctoral NRSA support. If the individual has already received 12 months of postdoctoral support under any NRSA grant or award, this form is not required. No Payback Agreement is required for predoctoral or prebaccalaureate trainees. For detail on NRSA payback, see Section IV.

3. Termination Notice (Form PHS 416-7)

The Termination Notice (Form 416-7) is the basis (along with the Statement of Appointment Form) for validating the total period of NRSA support and the amount of payback obligation (if any) for each NRSA trainee. For an institutional award, the awarding office sends the program director a supply of Termination Notices on an annual basis. The program director is responsible for the submission of a Termination Notice on each trainee immediately upon the termination of his/her support.

4. Consecutive Support

If a trainee switches from one NRSA grant mechanism to another, including from one awarding office to another, the requirement for payback service incurred is deferred until the total NRSA support is completed. All Statement of Appointment forms are reviewed to determine if previous NRSA support has been provided.

I. Progress Reports, Financial Status Reports, and Changes in the Project

1. Progress Reports

Progress reports must be submitted with all applications for non-competing continuation support in accordance with the instructions accompanying the application forms. Incomplete or inadequate progress reports may be returned for revision and may result in a delay of continued support. In addition, a final progress report must be submitted to the awarding office within 90 days after the end of a final competing segment of a project period.

2. Financial Status Report (FSR)

A FSR is required for all institutional grants no later than 90 days after the close of each budget period. This report will document the financial status of the grant according to the official accounting records of the grantee institution. Trainee stipends and tuition are obligated for the full 12-month appointment from the budget pe-

riod in which the appointment is initiated. Portions of stipends and tuition that extend beyond the budget period are carried over as unliquidated obligations. However, the report for the final budget period must have no unliquidated obligations and must indicate the exact balance of unobligated funds.

3. Changes in the Project

a. Changes in the program objectives as they relate to the area of research training for which the grant was approved require prior approval from the NIH awarding office.

b. Where absence of the program director is expected to exceed a continuous period of more than three months, plans for the conduct of the program during his or her absence must be approved in writing by the awarding office. Any proposed change of program director must be requested by the grantee institution and be approved in writing by the awarding office following review of the nominee's qualifications and re-evaluation of the project in the light of the proposed change.

c. Institutional grants are not transferred from one domestic institution to another except under most unusual circumstances. Such a change will generally be approved only if all of the major benefits attributable to the original grant can be transferred and there is no negative impact on trainees active in the program.

J. Other Terms and Conditions

1. Leave

a. Vacations and Holidays

Trainees may receive the same vacations and holidays available to individuals in comparable training positions at the grantee or sponsoring institution. Trainees shall continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters is generally considered an active part of the training period.

b. Sick Leave and Other Leave

Trainees may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the awarding office in response to a written request from the training program director or the sponsor. Sick leave may be used for the medical conditions related to pregnancy and childbirth.

c. Parental Leave

Trainees may also receive stipends for up to 30 calendar days of parental leave per year for the adoption or the birth of a child when those in comparable training positions at the grantee or sponsoring institution have access to paid leave for this purpose. Either parent is eligible for parental leave. For trainees, the use of parental leave must be approved by the training program director.

A period of terminal leave is not permitted and payment may not be made from grant funds for leave not taken.

d. Unpaid Leave

Individuals requiring extended periods of time away from their research training experience, which could include more than 15 calendar days of sick leave or more than 30 calendar days of parental leave must seek approval from the awarding office for an unpaid leave of absence. Approval for a leave of absence must be requested in advance by the training grant program director and be countersigned by an authorized institutional official.

During a leave of absence, documentation to suspend the period of appointment must be completed by submitting an amended Statement of Appointment Form and a Termination Notice. These forms should be submitted to the awarding office at the beginning of the leave. At the resumption of NRSA support, the reappointment must be documented on another Statement of Appointment Form.

2. Termination

A training grant may be terminated prior to its normal expiration date at the written request of the recipient, or by the Director, NIH, if it is found that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. In the event an award is terminated for cause, the Director, NIH, shall notify the awardee in writing of this determination, the reasons therefore, the effective date, and the right to appeal the decision.

3. Publications

Trainees are encouraged to submit reports of their findings for publication to the journals of their choice. Responsibility for direction of the project should not be ascribed to NIH. However, awarding office support must be acknowledged by a footnote in language similar to the following: "This Investigation was supported by National Institutes of Health, National Research Service Award (number) from the (awarding office)." In addition, it is now mandated that all grantees funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. 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.

4. Copyright

Except as otherwise provided in the conditions of the award, when publications or similar copyrightable materials are developed from work supported by NIH the author is free to arrange for copyright without awarding office approval. Any such copyrighted material shall be subject to royalty-free, nonexclusive, and irrevocable license to the Government to reproduce them, translate them, publish them, use and dispose of them, and to authorize others to do so for Government purposes.

5. Patents

No training grant made by NIH primarily to an awardee for educational purposes will contain any provision giving NIH any rights to inventions made by the awardee.

6. Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award may not be retained by the trainee/fellow. Such fees will be assigned to the grantee institution for disposition in accordance with NIH policy on grant-related (program) income (see "Administrative Requirements—Management Systems and Procedures—Program Income" in Part II of this policy statement). The term professional fees does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations. These fees, if within institutional policy, may be retained by the awardee.

7. Human Subjects/Animal Welfare/ Recombinant DNA

a. Human Subjects

The HHS regulations for the protection of human subjects 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 the HHS. If the applicant organization has an approved Assurance of Compliance on file with OPRR but, at the time of application, plans for the involvement of human subjects are so indefinite that Institutional Review Board (IRB) review and approval are not feasible, the grantee should check "Yes" and insert "Indefinite" on the face page of the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IRB review is already completed or an exemption is already designated. This review or exemption designation is sufficient, providing the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRG review dates or exemption designation.

For additional information on human subjects requirements, please refer to the Individual NRSA application kit or contact the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Blvd., Suite 3B01, Mail Stop Code 7507, Bethesda, MD 20892-7507, Telephone: (301) 496-7041.

b. Vertebrate Animals

The *PHS Policy on Humane Care and Use of Laboratory Animals* requires that grantee institutions (foreign or domestic) proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Protection from Research Risks (OPRR), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by NIH. If the applicant organization has an approved Assurance of Compliance on file with OPRR but, at the time of application, plans for the involvement of vertebrate animals are so indefinite that Institutional Animal Care and Use Committee (IACUC) review and approval are not feasible, the grantee should check "Yes" and insert "Indefinite" on the face page of the application. If an award is made, vertebrate animals may not be involved until verification of the IACUC approval date has been submitted to the NIH awarding office.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IACUC review is already completed. This review is sufficient, providing the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC review dates.

For additional information on vertebrate animals requirements, please refer to the PHS 398 application kit or contact the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Blvd, Suite 3B01, Mail Stop Code 7507, Bethesda, MD 20892-7507, Telephone: (301) 496-7163.

c. Recombinant DNA

The current *NIH Guidelines for Research Involving Recombinant DNA Molecules* and announcements of modifications and changes to the Guidelines are available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, MD 20892. All research involving recombinant DNA techniques that is supported by the HHS must meet the requirements of these Guidelines.

IV. Payback Reporting Requirements for Recipients

A. Purpose and Background

The National Research Service Award (NRSA) legislation requires some recipients of support to pay back the Federal Government by engaging in health-related biomedical or behavioral research including the direct administration or review of health-related research, health-related teaching, or any combination of these activities. Recent policy changes have significantly broadened the definition of "health-related." See Section C.1.a.(3) for a complete interpretation.

The National Institutes of Health (NIH) Revitalization Act of 1993, signed into law on June 10, 1993, includes provisions in Section 1602 that substantially modify the service payback requirement for individuals supported by the NRSA. For research training grants, these new provisions are applicable to all new appointments or re-appointments on or after June 10, 1993. For individual fellowships, these provisions apply to

all fellowship awards beginning on or after June 10, 1993. For competing fellowships, the award beginning date refers to the award activation date.

An individual who was appointed to a research training grant or who had a fellowship award activated before June 10, 1993 would be governed by the service payback provisions in effect at the time of the appointment or award until the end of that appointment or budget period.

B. Implementation

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

1. Prior to August 13, 1981

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

2. Effective August 13, 1981

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

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

3. Effective June 10, 1993 (NIH Revitalization Act):

a. Predoctoral Recipients

For **predoctoral** trainees beginning appointments and for **predoctoral** fellows activating awards on or after June 10, 1993, no payback obligation is incurred. Thus a Payback Agreement Form (PHS 6031) is no longer required.

b. Postdoctoral Recipients

For **postdoctoral** recipients, a payback obligation is incurred for the first 12 months of NRSA support with the 13th and subsequent months of **postdoctoral** support serving to pay back this obligation on a month by month basis. A Payback Agreement Form (PHS 6031) is still required but only for the initial 12-month postdoctoral support period.

The requirements established by the Revitalization Act also provide that the 13th and subsequent months of postdoctoral NRSA supported research training will be used to discharge **any prior** postdoctoral NRSA service payback obligation. See Section IV.C.1.c., Initiation of Payback Service, for detailed changes effective with the Act.

c. Short-term Training

Any predoctoral short-term training would not incur a payback obligation. Postdoctoral short-term training would incur a payback obligation. Any support would accrue along with any subsequent postdoctoral support until the first twelve months was established. At that point, the 13th and subsequent months of support would serve to offset the obligation on a month-by-month basis. In the event that subsequent postdoctoral support was not received, the individual would have an obligation which would have to be paid back in the traditional manner.

C. Payback

The NIH awarding office generally assumes responsibility for handling payback activities once the Termination Notice has been submitted and accepted. For some awarding offices, the NIH NRSA Payback Service Center assumes this responsibility. Established in the National Institute of General Medical Sciences effective October 1, 1995, the Payback Service Center personnel represent the NIH's experts in the NRSA Payback arena. For those awarding offices participating in the Center, the authorities normally delegated to the awarding office are automatically delegated to the Chief, NRSA Payback Service Center.

Most NRSA recipients eventually fulfill their payback obligation by engaging in activities which are determined to be acceptable service. Some recipients fulfill their obligation via financial payback. On rare occasions waivers of the payback obligation are granted.

As indicated in Section IV.B above, the amount of a payback obligation incurred is solely dependent upon when NRSA support was received. Timing of NRSA support is also a factor on the type of service that qualifies as acceptable payback.

1. Service Payback

a. Definitions

For the purpose of fulfilling the NRSA service payback obligation, the following definitions apply:

(1) Research

Research is defined as an activity which involves the design of experiments, development of protocols, and collection and interpretation of data. In addition, review of original research or administration of original research which includes providing scientific direction and guidance to research may be acceptable if a doctoral degree and relevant research experience is required for individuals filling such positions. Such research can be conducted in an academic, government, commercial or other environment in either a foreign or domestic setting.

In addition, when consistent with the cumulative amount, type, and frequency of research or research training experiences, functions which involve analytic or other technical activities conducted in direct support of research, as defined above, will also satisfy the service payback obligation.

(2) Teaching

Teaching is an instructional activity that takes place in an organized educational or other instructional environment. Activities classified as teaching are generally carried out in a formal didactic setting but other activities will be considered if they are consistent with the certifying institution's policy on the definition of teaching responsibilities. Such teaching can be conducted at universities, professional schools, research institutes, teaching hospitals, primary schools, secondary schools or colleges. When calculating hours of teaching per week, it is permissible to include three hours of preparation time for each hour of direct instruction. Acceptable teaching activities must have a biomedical or health-related relevance.

(3) Health-Related

This incorporates a broad range of activities related to the description, diagnosis, prevention or treatment of disease from the most basic biomedical or behavioral research to the most applied or clinical research. In addition to fields usually considered to be directly related to human disease, activities in other fields such as agriculture, environmental sciences, biotechnology, and bioengineering will also be considered health related.

b. Time Commitment

All acceptable activities must be undertaken for periods that average at least 20 hours per week. Total employment in such activities averaging less than 20 hours per week cannot be counted

towards fulfilling the obligation except in cases of disability or other pressing personal or family circumstances such as child care or elder care responsibilities. It is not permissible for individuals otherwise engaged in full-time employment to engage in service payback activities at effort levels below 20 hours per week.

If less than 20 hours commitment per week is permitted, the total period of service obligation will be prorated. For example, an individual who owes 12 months of service and can devote only 10 hours per week to service payback activities due to a disability will be required to engage in such service for 24 months. These exceptions are rare and must receive prior approval from the awarding office.

c. Initiation of Payback Service

(1) Support Received Prior to NIH Revitalization Act

For NRSA recipients who incurred a payback obligation from support received prior June 10, 1993, payback service must be performed following completion of NRSA support. No amount or type of activity prior to or during the period of NRSA support will satisfy the NRSA service payback obligation. However, payback service may be initiated immediately after termination from NRSA if the research or teaching activities meet the criteria cited above.

(2) Support Received Post-NIH Revitalization Act

Beginning with awards operating under the NIH Revitalization Act (appointments on or after June 10, 1993), service payback obligations for postdoctoral recipients may be discharged in the following ways:

(a) By receiving an equal number of months of postdoctoral NRSA support beginning in the 13th month of such postdoctoral NRSA support;

(b) By engaging in an equal number of months of health-related research, training and/or teaching averaging more than 20 hours per week.

(c) Trainees and fellows beginning appointments for the 13th and subsequent month of POSTDOCTORAL NRSA support on or after June 10, 1993 will be engaging in service which will also satisfy **prior** postdoctoral NRSA service payback obligation. Post-award service in non-NRSA supported health-related research, training, and/or teaching, is creditable toward any NRSA service payback obligation.

(d) Individuals who have completed their predoctoral NRSA training and have an existing NRSA service payback obligation are still required to engage in service payback or make financial repayment. Postdoctoral NRSA support may **not** be used to satisfy an existing predoctoral payback obligation.

d. Source of Funding

The source of funds supporting an individual's service payback activity is not restricted beyond the fact that for predoctoral payback activities it must not be supported by NRSA. An individual could be supported by a PHS grant or from any non-NRSA Federal or non-Federal source. Unpaid service is also permitted.

e. Timing of Service Obligation

An individual must begin to undertake the payback service requirement within two years after the termination date of the individual's NRSA support unless an extension of time to begin payback has been approved by the awarding office (see Section IV.C.4.a).

2. Alternative Service

Alternative service in lieu of research and teaching was deleted by the Omnibus Budget Reconciliation Act of 1981. Individuals who entered the NRSA program on or after August 13, 1981, the date the Act was signed, are not eligible for alternative service. Individuals who entered the

NRSA before August 13, 1981 are governed by the alternative service provisions in effect when their appointment started. Additional information concerning alternative payback service is available from the awarding office.

3. Financial Payback

a. Policy and Principal Calculation

If any individual to whom the requirement for service is applicable fails to undertake or perform such services, the United States Government shall be entitled to recover from the individual the amount determined in accordance with the following formula plus interest:

$$A = O \quad \frac{(t-s)}{(t)}$$

Where "A" is the amount the United States is entitled to recover, "O" is the sum of total amount paid to the individual under the National Research Service Award support; "t" is the total number of months in service obligation, and "s" is the number of months of such obligation served.

The total paid to the individual under institutional grants and individual awards at domestic, non-federal sponsoring institutions is considered to be the stipend only. The total paid an individual under a fellowship award at a foreign sponsoring institution includes the payment for the round trip travel costs. The total paid an individual under a fellowship award at a Federal sponsoring institution includes any money expended from the institutional allowance provided for such purposes as health insurance, travel, tuition, and fees.

b. Interest & Interest Rate Calculation

NIH computes interest on the principal amount beginning on the date the U.S. became entitled to recover stipends. The interest rate is the rate fixed by the Secretary of the Treasury after taking into consideration prevailing consumer rates of interest. Accordingly, interest may be accruing on any NRSA obligation if the two-year grace period has passed, or if deferment has expired, or if service has terminated before completion of the payback obligation. The Department of the Treasury certifies NRSA interest rates on a quarterly basis. Interest is computed on a 360 day-a-year basis and is applied through the date of receipt. Any outstanding amount will continue to bear interest at the initial rate set by the Secretary of the Treasury until financial payback is complete.

Determination of the "date" which sets the applicable rate of interest is dependent upon the type of NRSA account received for collection. If Financial Payback is Voluntary, the signature date of the notification of voluntary payback is the "date" that determines the interest rate as well as the initiation of the three year repayment period. If Financial Payback is Involuntary, the "date" which determines the interest rate and the three-year repayment period is the date of expiration of the two-year period following the termination of NRSA support. For example, if during June 1991, OFM received an account reflecting January 31, 1989 as the termination date of NRSA support, the Government, lacking any documentation to the contrary, becomes entitled to financial payback effective February 1, 1991. The rate of interest applicable is determined based on the February 1, 1991 date and the total NRSA obligation is required to be fulfilled by January 31, 1994.

The amount to be recovered financially, as determined from the Termination Notice plus applicable interest, shall be paid to the United States within the three-year period following such date.

4. Extensions of Payback

The National Research Service Award legislation and the promulgating regulation (42 CFR Part 66) authorize the Secretary to make exceptions to certain requirements under the Act.

a. Extensions of the Two-Year Period to Initiate Payback

Frequently, an APAC is returned requesting an extension of the two-year period to initiate payback. Indication of valid plans to initiate payback soon after the two-year grace period may be good reason to grant an extension.

b. Basis for Extensions

The awarding office may extend the period for undertaking payback service or permit breaks in continuous service. These determinations are based on the following criteria:

(1) an extension or break in service is necessary so the individual may complete his or her research or clinical training;

(2) the individual is unable to complete the requirements within the specified period because of a temporary disability; or

(3) completion by the individual of the requirement within the specified period would involve substantial hardship to the individual and that failure to extend the period would be against equity and good conscience.

Reasons for an extension or break in service include such things as completing residency training, where clinical teaching or research are not an integral part of their training, or individuals seeking employment that would fulfill the payback requirements.

Requests must be made in writing (separate letter or Annual Payback Activities Certification (APAC)) to the awarding office, specifying the need for additional time and the length of the required extension.

c. Extension to Complete Payback Service

The awarding office may approve or disapprove requests to extend the period of payback service or permit breaks in continuous service. Decisions to permit breaks in service are based on the criteria described in Section IV.C.4.b above.

5. Waiver

a. Policy

The National Research Service Award legislation and the promulgating regulation (42 CFR Part 66) authorize the Secretary to make exceptions to certain requirements under the Act. For waiver requests, NIH may waive, in whole or in part, the payback obligation, upon determination that compliance by the individual is impossible or would involve substantial hardship, and enforcement of the obligation to that individual would be against equity and good conscience.

b. Waiver Criteria

Requests for waivers should be made in writing to the awarding office and explain the need for the waiver according to the following criteria:

(1) Compliance by an individual will be deemed impossible if the individual is permanently and totally disabled;

(2) In determining whether compliance would involve substantial hardship to the individual and would be against equity, the Director, NIH (or designee) shall take into consideration:

(a) the individual's financial resources and obligations at the time of request for a waiver;

(b) the individual's estimated future financial resources and obligations;

In rare cases, the following might also be considered:

(c) the reasons for the individual's failure to complete the requirements within the prescribed period, such as problems of a personal nature;

(d) the extent to which the individual has engaged in payback activities;

(e) whether the individual has received sufficient training to be qualified to perform such activities;

(f) the lack of employment opportunities appropriate to the individual's education and training; and

(g) any other extenuating circumstances.

(3) Any obligation of any individual toward payback will be canceled upon death of the individual.

D. Certification of Payback Activities

1. Annual Payback Activities Certification (Form PHS 6031-1)

a. Annual Certification

Payback service is certified through the use of the Annual Payback Activities Certification (APAC) form (PHS 6031-1). Individuals with an outstanding payback obligation, must complete an APAC annually until their payback obligation is fulfilled.

The APAC is sent by NIH approximately one year after the completion of NRSA support, if an individual has incurred a payback obligation. Payback service may be initiated within the first 12 months of termination even though trainees/fellows have up to 24 months to initiate payback. There is no penalty to those individuals who do not initiate payback within the first 12 months; however, it is critical that they complete an APAC form to ensure contact is maintained and addresses are current.

On this form, the individual will report the activity in which he or she was engaged for the preceding 12 months, within the specified "reporting period". These forms are to be returned within 30 days of the reporting period end date to:

Data Management Control Section, OER
National Institutes of Health
Rockledge II, Room 1010
6701 Rockledge Drive MSC 7715
Bethesda, MD 20817-7715

Forms are then forwarded to the awarding office who will then review the activity and make a decision on its acceptability and inform the former trainee/fellow of the decision. This process will continue annually until the individual's total payback obligation is satisfied.

b. Change of Address

Any change in the mailing address of a NRSA recipient must be reported promptly to the awarding office until the service obligation is fully discharged.

2. Breaks in NRSA Support

Sometimes a trainee/fellow will have a period of non-NRSA support between two NRSA awards. An appropriate activity performed during this period of time may count for payback purposes toward the first NRSA award. If the non-support period is six months or longer, the individual receives an Annual Payback Activities Certification (APAC) form through the regular mechanism. However, if the break is less than six months, an APAC will not be automatically mailed. If acceptable payback service was performed during the break, the individual may complete an APAC, which can be obtained from the awarding office, to document the payback service.

3. National Health Service Corps

Occasionally, an NRSA recipient will have previously been a National Health Service Corps (NHSC) scholar. Legislation provides authority for holders of both awards to pay back the obligation of the two sources of support concurrently. Therefore, activities which qualify as NRSA payback will also serve as payback for the NHSC obligation. However, no Legislative Allowance is provided for NHSC service; e.g., 36 months of NRSA support (prior to June 10, 1993) and 36 months of NHSC support would require 24 months of NRSA payback service and 36 months of NHSC service respectively. The awarding office monitors both obligations until they are both satisfactorily completed.

APPENDIX 1—NRSA FINANCIAL PROVISIONS

Costs are normally provided based on a 12-month budget period. Awards for less than 12 months are prorated accordingly.

A. STIPENDS

Reference: *NIH Guide for Grants and Contracts.*

Annual stipend levels apply to all individuals receiving support through Institutional or Individual NRSA grants and are published in the *NIH Guide for Grants and Contracts*. These levels also apply to Minority Access to Research Career (MARC) and Career Opportunities in Health (COR) programs. Supplementation, or retroactive adjustments, with NRSA funds to accommodate changes in stipend levels is unallowable. Note, the annual level for postdoctoral recipients is determined by the number of full years of relevant postdoctoral experience at the time of the appointment/award.

B. TRAINING RELATED EXPENSES (TRE)—Institutional Training Grants

Sometimes referred to as "Above the Line Costs" or "Other Expenses", TRE funds are awarded to help defray the costs of other training related expenses such as staff salaries, consultant costs, equipment, research supplies and staff travel. TRE is generally requested in a lump sum, based on the number of trainees requested in the application, and entered on the budget page without further stipulation. Current levels are up to $1,500 per year for each predoctoral trainee, and up to $2,500 per year for each postdoctoral trainee. The training related expenses for specialized programs such as MARC & COR are referenced in the specific program announcements.

C. INSTITUTIONAL ALLOWANCE—Individual Fellowships

Reference: *NIH Guide for Grants and Contracts*, Vol. 26, No. 1, January 10, 1997

Provided annually to help defray the costs for the individual fellow. Section II.G.2.a.(1) describes in detail what are considered acceptable costs for individual fellowships depending on the training site. Note however, beginning in FY97, for postdoctoral fellowships, tuition & fees (except health insurance), when applicable, are no longer included as part of the institutional allowance. That cost will be awarded in accordance with the tuition policy described below. The cost of self-only health insurance itself will continue to be charged to the Institutional Allowance.

1. For new, competing fellowships, funded in FY 97 and henceforth, institutional allowance will be provided for all years as follows:

Predoctoral: Up to $4,000. Note, many awarding offices provide individual predoctoral fellowships with a reduced institutional allowance (usually $2,000) since costs for tuition, fees and health insurance are awarded separately. Specific program announcements and/or awarding offices should be contacted for guidance.

Postdoctoral: Up to $4,000 (For fellows at non-federal, non-profit, or foreign institutions)

Up to $3,000 (For fellows at Federal laboratories or for-profit institutions)

2. For non-competing fellowships funded in FY97, institutional allowance will continue to be awarded at levels previously determined. For those grants involving tuition & fees (including health insurance), these costs will continue to be paid under the previous policy guidelines. For postdoctoral fellows these costs will continue to be part of the institutional allowance. For predoctoral fellows, specific programmatic guidelines should be consulted.

Predoctoral: Up to $4,000

Postdoctoral: Up to $3,000

D. TUITION AND FEES

References:

NIH Guide for Grants and Contracts, Vol. 25, No. 2, February 2, 1996

NIH Guide for Grants and Contracts, Vol. 25, No. 31, September 20, 1996

NIH Guide for Grants and Contracts, Vol. 26, No. 1, January 10, 1997

Beginning in FY96, the NIH announced a new policy for the reimbursement of tuition costs. **Note, applicant institutions are instructed to continue to request the full amount of these costs in competing applications. Awarding office staff will apply the reimbursement formula at the time of an award.**

1. Institutional Grants

a. For competing awards issued in FY96 and henceforth, combined costs of tuition, fees and self-only health insurance are reimbursed at the following per trainee rate: 100% of all costs up to $2,000 and 60% of costs above $2,000. Future years provide no escalation.

b. Non-competing awards funded in FY96 will continue to be reimbursed at established levels until such time as they recompete.

2. Individual Postdoctoral Fellowships

a. For competing awards issued in FY97 and henceforth, when applicable, tuition and fees (excluding health insurance) is reimbursed at the following rate: 100% of all costs up to $2,000 and 60% of costs above $2,000. Future years provide no escalation.

b. Non-competing awards funded in FY97 will continue to be reimbursed at previously established levels.

3. Individual Predoctoral Fellowships

Reimbursement of tuition and fees (including health insurance) varies among the NIH awarding offices. Therefore, specific program announcements and/or awarding offices should be contacted for guidance.

a. When tuition, fees and health insurance is awarded as a separate cost, for competing awards issued in FY97 and henceforth, this cost will be reimbursed at the following rate: 100% of all costs up to $2,000 and 60% of costs above $2,000. Future years provide no escalation.

b. Non-competing awards funded in FY97 will continue to be reimbursed at previously established levels.

E. SHORT-TERM TRAINING—Students in Health Professional School

Most short-term trainees are funded at the predoctoral stipend level. The current monthly level is $958. Up to $125 per month for each participating student may be requested to defray other costs of training such as staff salaries, consultant costs, research supplies, tuition, travel etc. Some NIH awarding offices provide short-term training at the postdoctoral level as well. Specific program announcements and awarding offices should be contacted for guidance.

APPENDIX 2—RECEIPT, REVIEW, AND AWARD SCHEDULE

Application Receipt Dates	Review and Award Schedule		
All *Institutional* National Research Service Awards*	**Scientific Merit Review**	**Advisory Council Review**	**Earliest Award**
January 10	June/July	September/October	December
May 10	October/November	January/February	April
September 10	February/March	May/June	July
***Individual* National Research Service Awards (Fellowships)**		**Initial Review Dates**	**Range of Likely Start Dates**
April 5		June/July	September/December
August 5		October/November	January/March
December 5		February/March	May/July

***Some Institutes have only 1 or 2 receipt dates for Institutional Training Grants. They are:**

Institute/Center	Application Receipt Date(s)
NIA	May 10
NIAAA	May 10
NIAID	September 10
NIAMS	May 10
NICHD	May 10
NIDA	May 10
NIDCD	May 10
NIDR	September 10
NEI	May 10
NIEHS	May 10
NHLBI	May 10
NHGRI	May 10
NIMH (except Office of AIDS)	May 10
NINDS	May 10
NINR	May 10

Applicants are encouraged to confirm the application receipt dates by calling the appropriate Institute or Center Review Office. Specific NRSA programs may change their receipt dates to complement Institute workloads.

APPENDIX 3—NRSA FORMS

Research Fellowship Activation Notices (PHS 416-5) are automatically mailed with applicable Notice of Grant Awards. Additional forms are available from the Grants Management Office of the awarding IC.

Statement of Appointment Forms (PHS 2271) are automatically mailed with applicable Notice of Grant Awards. Additional forms are available from the Grants Management Office of the awarding IC.

NRSA Payback Agreements (PHS 6031) are automatically mailed with applicable Notice of Grant Awards. Additional forms are available from the Grants Management Office of the awarding IC

NRSA Termination Notices (PHS 416-7) are automatically mailed with applicable Notice of Grant Awards. Additional forms are available from the Grants Management Office of the awarding IC.

NRSA Annual Payback Activities Certifications (PHS 6031-1) are automatically mailed annually to applicable recipients.

SUPPORT OF SCIENTIFIC MEETINGS (CONFERENCE GRANTS)

General

NIH supports scientific meetings, conferences, and workshops (hereafter "conferences") that are relevant to its scientific mission and to public health under the R13 and U13 activity codes. NIH's support of conferences is contingent on the interests and priorities of the individual ICs. Some ICs do not provide conference support. For those that do, the preaward process and budget guidelines may vary. For example, some ICs require submission of a letter of intent prior to submission of the application. Therefore, potential applicants are encouraged to contact the funding IC for specific information as well as to ensure compliance with presubmission requirements. All applications for conference support must be submitted at least 6 months prior to the scheduled start of the conference. Furthermore, awards must be issued prior to the start date of the conference.

Applicability

This section applies to domestic and international conferences. Some of the following policies differ from the coverage in Part II of this policy statement, while others are in addition to that coverage. The following subsections will indicate how they relate to Part II. If an area is not addressed in this section, the Part II coverage applies; e.g., program income.

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

Definitions

Scientific Meeting (Conference): A gathering, symposium, seminar, workshop, or any other organized, formal event where persons assemble to coordinate, exchange and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge.

International Conference: A scientific meeting so designated by its sponsor or one to which open invitations are issued on an equal basis to potential participants in two or more countries other than the U.S. or Canada. The meeting may be held in any country, including the U.S.

Domestic Conference: A scientific meeting held in the U.S. or Canada primarily for U.S. or U.S.-Canadian participation (even if foreign speakers are invited).

Eligibility

Any domestic organization eligible to receive grants from NIH, including scientific or professional societies, is eligible for a conference grant. Both domestic and international conferences may be supported; however, an international conference can be supported only through the U.S. representative organization of an established international scientific or professional society. In exceptional cases, when there is no U.S. representative organization, a grant to support a specific aspect of an international conference may be awarded directly to a foreign institution or international organization. An individual is not eligible to receive a grant in support of a conference.

Application

The PHS-398 is to be completed by an organization seeking NIH conference support. Supplemental instructions are available in the *NIH Guide for Grants and Contracts* notice on support of scientific meetings (Vol. 26, No. 15, May 9, 1997) at **http://grants.nih.gov/grants/guide**.

Public Policy Requirements and Objectives

In addition to any applicable public policy requirements and objectives specified in Part II, conference grant applicants must comply with the *"Guidelines on the Inclusion of Women, Minorities, and Persons with Disabilities in NIH-Sponsored and/or-Supported Intramural and*

Extramural Meetings and Conferences" (available through the NIH/OER Home Page at **http://grants.nih.gov/grants/oer.htm**). Appropriate representation of women, individuals who are members of racial/ethnic minority groups, persons with disabilities, and other individuals who have been traditionally underrepresented in science must be included in all aspects of planning, organization, and implementation of NIH-sponsored or -supported meetings. "Appropriate representation" is that based on the availability of scientists from these groups known to be working in a particular field of biomedical or behavioral research. If appropriate representation is not apparent, NIH will not make an award until the applicant has submitted acceptable documentation regarding its compliance.

Review

Applications will be reviewed for programmatic relevance and for merit using the following criteria:

- The need for, and timeliness of, the conference;
- Its format and agenda;
- Qualifications of the organizers and proposed participants;
- Past performance, where applicable;
- Appropriateness of the meeting site;
- Plans for the appropriate involvement of women, individuals who are members of racial/ethnic minority groups, and persons with disabilities, in the planning and implementation of the proposed conference (see "Public Policy Requirements and Objectives" in this section); and
- Appropriateness of the proposed budget, in accordance with IC guidelines.

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

Funding

Grants or cooperative agreements may be used to provide conference support. A cooperative agreement may be awarded if the IC determines that it needs to have substantial involvement in the planning and conduct of a conference. Awards in support of a single conference will be made for a project period commensurate with the time involved in planning and conducting the conference and post-conference follow-up, usually 1 year. A conference grant made to a permanently sponsoring organization for conferences held annually or biennially on a recurring topic may be awarded for up to 5 years in total and will be funded annually. Continued funding beyond the first year will be contingent on a satisfactory progress report submitted as part of a streamlined noncompeting award process. A shift in conference focus after the first year requires IC prior approval.

Allowability of Costs/Activities

The following specifies the types of costs that are generally allowable under conference grants. Although some of these reiterate coverage in Part II of this policy statement, **no costs other than those specified below are allowable under conference grants**. The following also highlights certain unallowable costs.

General Support: Grant funds may not be used to provide general support for international conferences held in the U.S. or Canada. In those cases, grant funds may be awarded to support only specific aspects of a conference. An example would be a selected symposium, panel, or workshop, including the costs of planning and travel of U.S. participants.

Alterations and Renovations: Grant funds may not be used to support A&R of any kind.

Conference Services: Grant funds may be used for necessary recording of proceedings, simultaneous translation, etc., and subsequent transcriptions.

Consultant Services: Grant funds may be used to pay consultant fees, including travel and supporting costs (per diem or, where applicable, subsistence).

Entertainment and Personal Expenses: Costs of amusement, diversion, social activities, ceremonials, and related incidental costs, such as bar charges, tips, personal telephone calls, and laundry charges of participants or guests, are unallowable. (Also see "Meals" immediately below.)

Equipment: Grant funds may be used for the rental of necessary equipment but may not be used for the purchase of equipment.

Facilities and Administrative Costs: F&A costs will not be allowed on grants in support of conferences.

Federal Employees: See "Grants to Federal Institutions and Payments to (or on Behalf of) Federal Employees under Grants." in this Part.

Honoraria: Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or administration may not be paid from grant funds. However, speakers fees for services rendered are allowable.

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

Membership Dues: Not allowable.

Publication Costs: When grant funds are awarded to pay for either the entire or partial cost of publication of proceedings or a book or pamphlet, these costs are considered to cover special plates, charts, diagrams, printing, distribution, mailing, postage, and general handling, unless otherwise specified at the time the grant is awarded.

Registration Fees: Registration fees, when paid by the grantee to other organizations on behalf of attendees, may be paid from grant funds, provided such fees cover only those allowable costs properly chargeable to the grant.

Research Patient Care: Not allowable.

Salaries: In accordance with the policy of the grantee organization, grant funds may be used for salaries, in whole or in part, of professional personnel, clerical assistants, editorial assistants, and other nonprofessional staff in proportion to the time or effort spent directly related to the conference.

Supplies: Grant funds may be used for the purchase of supplies for the conference, provided the supplies are received and used during the budget period

Travel: Funds may be used for the travel of staff, speakers, participants, and attendees if identified in the application and approved at the time of award. Travel expenses for employees of the grantee organization are governed by the grantee's travel policies, consistently applied regardless of the source of funds.

Any U.S. foreign travel restrictions that are in effect at the time of the award will be followed, such as:

- Limitations or restrictions on countries to which travel will be supported.
- Budgetary or other limitations on availability of funds for foreign travel.

Proposed per diem or subsistence allowances must be reasonable and limited to the days of attendance at the conference plus the actual travel time to reach the conference location by the most direct route. Where meals and/or lodgings are furnished without charge or at a nominal cost (e.g., as part of the registration fee), the pro-

posed per diem or subsistence allowance must take this into consideration.

Transportation costs for attendees and participants at the conference may not exceed coach class fares. In all cases, U.S. flag carriers will be used where possible.

Grant funds may not be used to pay per diem or expenses other than local mileage for local participants in the conference.

Costs associated with obtaining visas and passports are not allowable charges to the grant.

Administrative Requirements

Intellectual Property: Publications and Copyright

If the grantee organization wishes to publish material for which support has been provided in whole or in part with NIH funds, the material may be distributed free of charge. If the grantee organization charges for the material, the sales proceeds are considered program income, and must be accounted for as specified in the NGA and reported on the Financial Status Report (see "Reporting and Record Retention" in this section).

Unless otherwise provided in the terms and conditions of the award, the grantee is free to arrange for copyright of any publication resulting from an NIH-supported conference. However, any such copyrighted publication shall be subject to a nonexclusive, irrevocable, royalty-free license to the Government to reproduce, translate, publish, and dispose of the material and to authorize others to use the work for Government purposes. Copyright does not extend to any materials prepared by Federal employees as part of their official duties.

Reporting and Record Retention

Grantees are responsible for submitting the following reports to the IC upon completion or termination of a grant in support of a conference:

Progress Report

For single conferences, a final report of the conference must be submitted to the awarding IC within 90 days after the conference. The report should include the following:

- Grant number;
- Title, date, and place of the conference;
- Name of the person shown on the application as the conference director, principal investigator, or program director;
- Name of the organization that conducted the conference;
- A list of the individuals, and their institutional affiliations, who participated as speakers or discussants in the formally planned sessions of the meeting; and
- A summary of topics discussed/ conclusions.

With the approval of the IC, copies of proceedings or publications resulting from the conference(s) may be substituted for the final report, provided that they contain the information specified above.

Expenditure Report

A Financial Status Report is required from the grantee within 90 days after the completion of the project period. Records of expenditures must be maintained in accordance with the provisions of 45 CFR 74.53 or 92.42 (see "Administrative Requirements—Monitoring—Record Retention and Access").

CONSORTIUM AGREEMENTS

General

The grantee, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the grantee, as specified in this policy statement. This section includes the requirements for an applicant/grantee under "consortium agreements" in which the grantee collaborates with one or more other organizations in carrying out the grant-supported research. In general, the requirements that apply to the grantee also apply to the consortium participant(s) with the exceptions noted below. Recipients of Small Business Technology Transfer (STTR) grants should follow the specific requirements for research collaboration established for that program (see "Grants to For-Profit Organizations").

Under consortium agreements:

- The award will be made to a single grantee with a single PI, even though one or more organizations other than the grantee will carry out portions of the planned programmatic activity.
- The grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.

Applicants are expected to detail their proposed collaborations as part of the grant application. If the application is approved as submitted, no further approval is required unless, during performance, the grantee plans to undertake additional or alternative collaborations that would constitute a change in the scope or objectives of the approved project (see "Administrative Requirements—Changes in Project and Budget" in Part II).

Whether proposed at the application stage or subsequent to award, the following information must be provided to NIH for review and approval:

- A list of all proposed performance sites both at the applicant/grantee organization and at the consortium participant(s);
- Complete application budget pages (for the first year and each future year of support requested) for each consortium participant; and
- The following statement, accompanied by the signatures of the authorized institutional officials (or equivalent) of the applicant and consortium participants:

> "The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy."

NIH may request additional information prior to award and may place a special condition(s) on the award.

Administrative and Other Requirements

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

Public Policy Requirements and Objectives

The grantee is responsible for determining whether a consortium participant has filed assurances with NIH that would cover its activities within the consortium and, if not, for ensuring that any required assurances or certifications are

submitted to NIH. See "Public Policy Requirements and Objectives" in Part II for the full statement of these requirements and their applicability to consortium participants.

Application of Cost Principles

The cost policies that apply to research grants as described in "Cost Considerations—Allowability of Costs/Activities" in Part II apply, in general, to consortium agreements.

Approval Authorities

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

Tangible Personal Property

Exempt Property

If the grantee provides exempt property or authorizes a consortium participant to purchase property that would be considered exempt if acquired by the grantee, the grantee may vest title in the consortium participant or may reserve the right to do so at a later time. The grantee may also establish its own disposition and accountability requirements, provided they are consistent with the transfer rights of NIH (see "Administrative Requirements—Management Systems and Procedures—Property Management System Standards—Equipment and Supplies").

Nonexempt Property

If the grantee provides nonexempt property or authorizes a consortium participant to purchase property that would be considered nonexempt if purchased by the grantee, title to such property must remain with the grantee or be vested in the grantee upon acquisition of the property. The grantee may establish use, accountability, and disposition requirements for the property, provided they are consistent with, and do not impair, the grantee's ability to comply with the requirements of 45 CFR 74 or 92, as appropriate.

Intellectual Property

See "Administrative Requirements—Availability of Research Results: Publications and Intellectual Property Rights, Including Unique Research Resources," and 37 CFR 401 for policies governing consortium agreements and the rights of grantees and consortium participants.

Program Income

Consortium participants are expected to comply with NIH requirements for program income reporting and disposition, consistent with the terms of the grant award from NIH.

Audit

The grantee must require consortium participants to comply with the requirements of OMB Circular A-133 or 45 CFR 74.26(d), as applicable, for audit of NIH grant funds expended by consortium participants. A consortium participant may be a direct NIH grantee or contractor or may be receiving funds only under the consortium. Regardless, if a consortium participant meets the OMB Circular A-133 threshold criterion of expenditures exceeding $300,000 under applicable Federal awards, the grantee must receive a copy of that organization's A-133 audit and take appropriate action based on any findings that relate to the consortium agreement. If a consortium participant will not reach that threshold, the grantee is responsible for monitoring the organization's activities to ensure compliance with NIH requirements. The grantee may not require a consortium participant to have an audit and charge the audit costs to NIH grant funds unless required or authorized by OMB Circular A-133 or 45 CFR 74.26(d).

Written Agreement

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

- Identification of the PI and individuals responsible for the research activity at each consortium participant along with their roles and responsibilities;

- Procedures for directing and monitoring the research effort;

- Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, and procedures for review and approval of expenditures of grant funds at each organization;

- If different from those of the grantee, a determination of policies to be followed in such areas as travel reimbursement and salaries and fringe benefits. The policies of the consortium participant may be used as long as they meet NIH requirements;

- Incorporation of those generally applicable requirements included in Part II of this policy statement and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances (see "Public Policy Requirements and Objectives").

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

- A provision making the inventions and patent policy (see "Administrative Requirements—Availability of Research Results: Publications and Intellectual Property Rights, Including Unique Research Resources") applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the grantee can fulfill its responsibilities to NIH. The grantee should also obtain appropriate patent agreements from all persons who perform any part of the work under the grant and may be reasonably expected to make inventions, and agreements to govern disposition of rights to inventions resulting from screening compounds synthesized under the grant; and

- As appropriate, provisions regarding property, program income, publications, reporting, and audit necessary for the grantee to fulfill its obligations to NIH.

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

General

Most of the policies contained in Part II of this policy statement apply to NIH grants made to foreign institutions and international organizations (hereafter "foreign grants"), including the requirements of 45 CFR Part 74 or 92 and the cost principles. If an applicant/grantee would be unable to comply with these requirements, the authorized organizational official should contact the GMO. Specific exceptions and modifications of requirements for foreign grants, as well as certain highlighted policies, are set forth below. This section also includes policies that apply to domestic grants with a substantial foreign component. It does not apply to agreements under the U.S. Special Foreign Currency Program.

Eligibility

In general, foreign institutions and international organizations, including public or private nonprofit or for-profit organizations, are eligible to receive research project grants. Foreign institutions and international organizations are not eligible to receive Institutional National Research Service Awards, program project grants, center grants, resource grants, SBIR/STTR grants, or construction grants. However, some mechanisms, such as research project grants (R01s), may support projects awarded to a domestic institution with a substantial foreign component. For purposes of this policy, a "substantial foreign component" is defined as performance of any significant element or segment of the project outside the U.S. either by the grantee or by a researcher employed by a foreign institution, whether or not grant funds are expended. Activities that would meet this definition include:

- The involvement of human subjects/or animals.
- Extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities.
- Any activity that may impact on U.S. foreign policy through the involvement of grantee project staff in the affairs or environment of the foreign country.

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

See "Support of Scientific Meetings (Conference Grants)" in this Part for NIH policy on support of international conferences.

Grants may not be made to individuals in a foreign location (i.e., outside of the U.S. and its territorial possessions). Occasionally, a fellowship award is made to an American citizen or a non-citizen national to study in a foreign institution. (A "non-citizen national" is a person who although not a citizen of the U.S. owes permanent allegiance to the U.S., such as a resident of American Samoa.)

Review

Applications from foreign institutions will be evaluated and scored during the initial review process using the standard review criteria. In addition, the following will be assessed as part of the review process and award decision:

- Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the U.S. or that augment existing U.S. resources.
- Whether the proposed project has specific relevance to the mission and objec-

tives of the awarding IC and has the potential for significantly advancing the health sciences in the U.S.

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

Public Policy Requirements and Objectives

Several of the public policy requirements and objectives are highlighted below. A complete listing of public policy requirements and objectives and their applicability to foreign grants is contained in Table 2 in Part II.

Misconduct in Science. This public policy requirement, including its requirement for an assurance, applies to foreign grants.

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

Human Subjects. The human subjects requirements contained in "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects," including the requirement for an Assurance of Compliance pursuant to 45 CFR Part 46, apply to foreign grants. Foreign grantee organizations and foreign consortium participants under domestic or foreign grants must submit an Assurance of Compliance if human subjects are involved.

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

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

Lobbying. The requirements of "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying," including disclosure reporting, apply to foreign grants.

Debt. Foreign applicants are required to provide a certification of non-delinquency on debts owed to the United States as specified in "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Nondelinquency on Federal Debt."

Debarment and Suspension. Applicants/grantees that are foreign governments or governmental entities, public international organizations, or foreign-government-owned or -controlled (in whole or in part) entities are not required to submit the certification concerning suspension or debarment and are not subject to suspension or debarment under 45 CFR Part 76. All other foreign institutions and international organizations are subject to these requirements.

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

Funding and Payment

The initial project period and any subsequent competitive segment may not be authorized for more than 5 years each.

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

Awards to foreign institutions and international organizations are not paid through the HHS Payment Management System (PMS). These grants will normally be paid by U.S. Treasury check by the NIH Office of Financial Management (OFM) on a predetermined quarterly advance basis, usually in four equal installments. If the amount advanced to an organization based on the predetermined quarterly advance is insufficient to meet the grant's cash requirements, the grantee must make a written request to the IC GMO for any additional funds needed. All payments will be in U.S. dollars. Foreign grantees are strongly encouraged to use U.S. banks to ensure that payments arrive on time.

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

Allowability of Costs/Activities

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

Alterations and Renovations: Unallowable.

Customs and Import Duties: Unallowable. This includes consular fees, customs surtax, value-added taxes, and other related charges.

Facilities and Administrative (F&A) Costs: With the exception of the American University, Beirut, and the World Health Organization, F&A costs will not be paid (either directly, under a consortium agreement, or through a contract under a grant) to an organization located outside the territorial limits of the U.S. or an international organization regardless of location.

Administrative Requirements

Changes in Project and Budget

Foreign grants are included in expanded authorities. Inclusion in the Streamlined Noncompeting Award Process (SNAP) is at the discretion of the IC and will be specified on the NGA.

Change in Scope or Objectives

A change in the performance site within a foreign country or performance in a country other than that specified in the approved application is considered a change in project scope or objectives and requires NIH prior approval. The proposed addition or elimination of a substantial foreign component under a grant to a domestic institution is considered a change in scope or objectives requiring NIH prior approval.

Change of Grantee Organization

A change of grantee that involves the transfer of a grant to or between foreign institutions or international organizations requires competitive review and approval of the IC Advisory Council/Board. Transfer of a grant from a foreign organization to a domestic organization requires the approval of the GMO.

Audit

Foreign grantees have the same options (specified in 45 CFR 74.26(d) and in "Grants to For-Profit Organizations" in this Part) as for-profit organizations concerning audit.

Reporting and Record Retention

Foreign grantees must submit annual FSRs (SF-269) in U.S. dollars. The currency rate in existence at the time the FSR is prepared should be used in preparing the report. Record retention requirements are the same as those for domestic grantees.

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

General

NIH may award grants to Federal entities. Although the activity under these grants will take place in a research environment, certain terms and conditions vary from those included in Part II of this policy statement due to the recipient's status as a Federal institution. This section specifies those differences as well as differences in treatment among different Federal institutions. In addition, this section addresses the policies that apply to payments to (or on behalf of) Federal employees under grants, including grants awarded to organizations other than Federal institutions.

Eligibility

Federal institutions are, in general, eligible to receive NIH grants, including research project grants and training grants. Federal institutions must also meet the eligibility requirements of the grant program from which support is sought. PHS organizational segments, other than PHS hospitals, may receive NIH grant support under exceptional circumstances only. Such circumstances may include situations where a project cannot be supported within the mission of the applicant PHS agency or organizational segment, the activity cannot be performed elsewhere, its non-pursuit would have an adverse or potentially important impact on the NIH mission, and a grant is determined to be the appropriate means of carrying out the activity. However, NIH may not award a grant to an NIH component.

Although the performance site may be at a level lower than the agency or department level of the Federal institution, when an award is made to an eligible Federal institution, the Federal agency or department will be the designated grantee and must assume responsibility for the project. A Federal institution must also ensure that its own authorizing legislation will allow it to receive NIH grants and to be able to comply with the award terms and conditions.

A document certifying both the assumption of responsibility and authority to receive a grant must accompany each new and competing continuation application. The certification must be signed by the head of the responsible Federal department or independent agency or a designee who reports directly to the department or agency head. (In the case of the Department of Defense, the Departments of the Army, Navy, and Air Force shall be considered the Federal department; and their Secretaries, the responsible Department head.) This certification is in addition to any certifications that are made by the authorized institutional official's signature on the face page of the application. The certification requirement does not apply to Department of Veterans Affairs' Medical Centers (VAMC), Bureau of Prisons' (Department of Justice) hospitals, PHS hospitals (including Indian Health Service hospitals), or other PHS organizational segments.

Investigators with joint appointments at the Department of Veterans Affairs (VA) and an affiliated university must have a memorandum of understanding (MOU) that specifies the title of the PI's appointment, the responsibilities (at both the university and the VA) of the proposed PI, and the percentage of effort available for research. The MOU must be signed by the appropriate officials of the grantee organization and the VAMC and must be updated at least annually. Under this model, there is no involvement of a VA-affiliated non-profit research corporation (VANPC). The joint VA/university appointment of the investigator constitutes 100 percent of his or her total professional responsibilities.

Payment

Under NIH grants, the Department of Defense will normally be paid by U.S. Treasury check after submission of the appropriate interagency

form to the Office of Financial Management, NIH. Payments to all other Federal departments and agencies will generally be accomplished by transfers of funds between appropriations.

Allowability of Costs/Activities

The allowability of costs under grants to Federal institutions shall be determined by the established policies of the institution consistently applied to both its own activities and to grant-supported activities and the following. In the absence of a governing institutional policy, the cost principles for State, local, and Indian tribal governments (OMB Circular A-87) will apply.

Salaries: See "Federal (U.S. Government) Employees" immediately below.

Institutional Allowances under Fellowships: Institutional allowances may be requested by Federal institutions sponsoring a predoctoral or postdoctoral fellow unless otherwise restricted by law or regulation.

Facilities and Administrative Costs: F&A costs will not be provided to Federal institutions.

Federal (U.S. Government) Employees: Whether or not costs will be charged to the grant, when a Federal employee will be involved in an NIH grant-supported activity in any capacity other than as an employee working on a grant to a Federal institution, an outpatient, or a study subject, special conditions apply as provided in this subsection. The limitations in this subsection do not apply to individuals that are part-time Federal employees because of service on advisory groups or a formal consulting arrangement with a Federal agency. (See the HHS Standards of Conduct at 45 CFR 73, Subpart J for additional guidance.)

The following four specified types of costs are the only ones that can be charged to NIH grants on behalf of Federal employees, and only under the conditions specified. Applicants/recipients should advise any Federal employees with whom these types of arrangements may be made to consult with their employing agency concerning their ability to meet the required conditions. The applicant organization must submit, as part of the grant application, any letters or documentation specified below, and that documentation must be deemed acceptable by the awarding office GMO prior to the Federal employee's involvement in the project.

Consultant fees are allowable only for medical personnel of the Uniformed Services of the United States (excluding PHS Commissioned Officers) and when all of the following conditions are present:

- The employees are providing the kind and extent of medical services approved in the grant award;
- Adequate numbers of qualified civilian personnel are not available to provide these services, and eligible Federal medical personnel are hired only in addition to those qualified civilian medical personnel, if any, who are available; and
- The applicant organization provides prior written authorization from the proposed consultant's commanding officer that he or she is authorized to work on the grant-supported activity during non-duty hours or while on authorized leave, and can be paid for his or her efforts.

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

Salary or Fringe Benefits

Except as provided below, under a grant to a Federal institution, no salary or fringe benefit payments may be made from NIH grant funds to career, career-conditional, or other Federal employees (civilian or uniformed services) with permanent appointments provided for under existing position ceilings of a given Federal component. While the level of effort required for the

research project must be allowed by the employing agency as part of the individuals' official duties, under a grant to a Federal institution, salary costs associated with an individual participating in an official capacity as a Federal employee are not allowable costs under the NIH grant. Payments to temporary employees specifically hired to assist in the performance of an NIH grant are allowable.

Under grants to VANPCs, if the PI is a part-time VA employee, NIH grant funds may be used to pay the differential between the individual's VA part-time salary and the salary level for a full-time VANPC commitment, in accordance with the established policies and salary structure of the VANPC.

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

1. A PHS Commissioned Officer or a civil service employee carrying out duties for which specific legislative authorization exists permitting direct Federal assistance in lieu of cash under the grant or where the Government is reimbursed for services rendered subject to restrictions applicable to such personnel, including the applicable Federal standards of conduct (for HHS, 45 CFR Part 73).

2. A PHS Commissioned Officer on leave-without-pay (LWOP) if

a. The grantee has obtained written prior approval from the NIH awarding office;

b. The total amount of salary paid from NIH grant funds is proportional to the time devoted to the project and does not exceed the total annual amount of pay and allowances the individual would have received if not in LWOP status; and

c. The parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest other violations of the applicable standards of conduct.

3. A civil service employee participating in a grant to a non-Federal organization and the following conditions are met:

a. The individual is participating as part of an approved Intergovernmental Personnel Act (IPA) assignment in a role other than as PI. IPA assignments generally do not exceed 2 years and may not exceed 4 years of continuous duration (5 U.S.C. 3372). Based on this statutory time limitation, the involvement of the civil service employee should be limited in scope. Therefore, the proposed PI and other key personnel, as determined by the NIH awarding office, are not permitted to participate in NIH grant activities while serving under an IPA.

b. Prior to making any payment from NIH grant funds to such an employee, the grantee must certify that the employee(s) is on an IPA assignment and must provide adequate documentation, as determined by NIH, of the IPA assignment and information about its nature and duration.

c. The level of effort required for the research project must be allowed by the employing agency as part of the individuals' official duties. Salary payments from NIH grant funds must be proportional to the time an individual devotes to the grant-supported project. The total salary support may not exceed the normal level of compensation of Federal salary if the individual was not participating in the grant.

d. The parties concerned have made a prior determination that there is no possibility of dual compensation and no actual or ap-

parent conflict of interest or other violation of the applicable standards of conduct.

Travel costs are allowable if the employee is:

- Working under a grant to a Federal institution;
- Performing allowable reimbursable services as specified under 1., 2. or 3. immediately above; or
- Attending an NIH grant-supported conference during non-duty hours; while in a pre-existing LWOP status or one that continues beyond the conference; or on detail to a State or local government, educational institution, or other non-profit organization, provided such payments are made in accordance with established institutional policy, consistently applied regardless of the source of funds, and the parties concerned have taken reasonable steps to ensure that there is no actual or apparent conflict of interest.

Administrative Requirements

Equipment Accountability

NIH will consider all property acquired under a grant awarded to a Federal institution as exempt (see 45 CFR 74.33) for purposes of determining the accountability requirements of 45 CFR 74.34. However, for items of equipment having a unit acquisition cost of $5,000 or more, NIH has the right to require transfer of the equipment, including title, to NIH or to an eligible third party named by the IC under the conditions specified in 45 CFR 74.34.

Procurement Requirements

Procurement under grants to Federal institutions is governed by the *Federal Acquisition Regulation (*FAR) and the recipient agency's FAR supplement.

Intellectual Property: Inventions and Patents

Inventions resulting from grants supporting the activities of Federal employees under grants to Federal institutions shall be reported simultaneously to NIH pursuant to the terms of the award and to the employing agency under the terms of Executive Order 10096, as amended, and are subject to the licensing requirements of 37 CFR Part 501.

GRANTS TO FOR-PROFIT ORGANIZATIONS

General

Some of the terms and conditions for grants to for-profit (commercial) organizations vary from the standard terms and conditions included in Part II of this policy statement. In addition, the terms and conditions of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs vary from those otherwise applicable to for-profit organizations. This section addresses separately the policies applicable to for-profit organizations, generally, and to SBIR and STTR awards. If an exception is not stated below or in the NGA, the terms and conditions specified in Part II of this policy statement apply, including requirements for the protection of human subjects and animal welfare.

Eligibility

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

Allowability of Costs

Cost Principles

There are no cost principles specifically applicable to grants to for-profit organizations. Therefore, the cost principles for commercial organizations set forth in the *Federal Acquisition Regulation*, 48 CFR Part 31.2, will generally be used. For proprietary hospitals, the cost principles in 45 CFR Part 74, Appendix E, will be used.

Profit or Fee

Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a for-profit organization, whether as a grantee or as a consortium participant. A profit or fee may be paid to a contractor providing routine purchased goods or services. A profit or fee is considered to be an amount in excess of actual allowable, allocable, and reasonable direct and indirect (F&A) costs.

Independent Research and Development Costs

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

Facilities and Administrative Costs (Indirect Costs)

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

Administrative Requirements

For-profit organizations are generally subject to the same administrative requirements as non-profit organizations, including those relating to property title and management. Exceptions to those requirements for for-profit organizations are described below.

Intellectual Property: Inventions and Patents

As described in "Administrative Requirements—Availability of Research Results: Publications and Intellectual Property, Including Unique Research Resources," the requirements set forth in 37 CFR Part 401 govern the development, reporting, and disposition of rights to inventions and patents resulting from all NIH grants to for-profit organizations, whether small businesses or large businesses (see Part II for the full text of the clause). Additional information about the requirements of 37 CFR 401 should be obtained from the Inventions and Extramural Reporting Branch, OPERA, NIH (see Part IV for addresses and telephone number).

To the extent authorized by 35 U.S.C. 205, the Government will not make public any informa-

tion disclosing a Government-supported invention for a reasonable period to allow the grantee time to file a patent application, nor will the Government release any information that is part of that patent application. See the SBIR/STTR subsection for requirements specific to those programs.

Disposition of royalties or licensing fees earned on patents and inventions arising out of activities developed under NIH grants shall be governed by determinations made or agreements entered into under 37 CFR Part 401. Invention reporting requirements for for-profit organizations are those specified in "Administrative Requirements—Monitoring—Reporting—Invention Reporting."

Program Income

For-profit grantees other than those under the SBIR/STTR programs are subject to the deductive alternative for the use of program income described in "Administrative Requirements—Management Systems and Procedures—Program Income" and in 45 CFR 74.24(b).

Operating Authorities

The operating authorities (expanded authorities or standard NIH authorities) for awards issued to for-profit organizations are usually determined by the support mechanism (see "Administrative Requirements—Changes in Project and Budget").

Audit

HHS has specified the requirements for non-Federal audits of for-profit organizations in 45 CFR 74.26(d). A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $300,000 or more under one or more HHS awards and at least one of those awards is an HHS grant (as a direct grantee and/or under a consortium agreement). 45 CFR 74.26(d) essentially incorporates the thresholds and deadlines of OMB Circular A-133 but provides for-profit organizations two options regarding the type of audit that will satisfy the audit requirements. The grantee may either have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), GPO stock # 020-000-00-265-4, of all the HHS awards; or (2) an audit that meets the requirements of OMB Circular A-133.

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

The Government Auditing Standards are available electronically at **http://www.ignet.gov/ignet/internal/manual/yellow/yellow.html**.

Audits shall be completed and submitted to the following office within a period of time that is the earlier of (1) 30 days after receipt of the auditor's report(s), or (2) 9 months after the end of the audit period, i.e., the organization's fiscal year. The address is:

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

For-profit organizations spending less than $300,000 a year (calculated as above) are not required to have an annual audit for that year but must make their grant-related records available to NIH or other designated officials for review or audit.

Small Business Innovation Research and Small Business Technology Transfer Programs

NIH is currently required by statute to reserve a portion of its annual extramural budget for projects under the SBIR and STTR programs. These programs are primarily intended to emphasize increased private sector commercialization of technology and to increase small business participation in federally funded research and development (R&D).

Both the SBIR and STTR programs consist of the following three phases:

- Phase I: The objective of this phase is to establish the technical merit and feasibility of proposed research or R&D efforts and to determine the quality of performance of the grantee (small business concern) prior to providing further Federal support in Phase II.

- Phase II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding will be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. (Only Phase I grantees are eligible to receive Phase II funding. Phase II applications may be submitted after the Phase I award is made, and NIH expects they will be submitted within the first six receipt dates following expiration of the Phase I budget period; i.e., normally 2 years beyond the expiration date of the Phase I award).

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

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

- The STTR program requires a small business concern (applicant organization) to "team" with a research institution to collaboratively conduct a project that has potential for commercialization. The SBIR program does not have this requirement, i.e., the small business concern may conduct the entire project without outside collaboration or with outside collaboration within the limits described under "Eligibility" in this section.

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

Eligibility

Each organization receiving a grant under the SBIR/STTR programs must qualify as a small business concern. Under SBIR/STTR requirements, in determining whether the organization is a small business concern, NIH will assess several factors, including:

- Whether the small business is independently owned and operated; and

- Whether it is an affiliate of a larger organization whose employees, when added to those of the applicant organization, do not exceed 500.

In conducting this assessment, all appropriate factors will be considered, including common ownership, common management, and contractual relationships.

In accordance with 13 CFR Part 121.103, affiliation exists when, either directly or indirectly, (1) one concern controls or has the power to control the other, or (2) a third party or parties controls or has the power to control both. One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space and/or employees

and/or other facilities (e.g., laboratory space). The research and analytical work performed by the grantee organization is to be conducted in research space occupied by, available to, and under the control of, the SBIR/STTR grantee. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR grantee has entered into a consortium agreement or contractual arrangement with another organization for a specific, limited portion of the research project.

Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business concern.

For both Phase I and Phase II SBIR/STTR awards, the research or R&D project activity must be performed in its entirety in the U.S. (The U.S. is defined as the 50 States, the territories and possessions of the United States, the Commonwealth of Puerto Rico, the Federated States of Micronesia, the Republic of Palau, the Republic of the Marshall Islands, and the District of Columbia.)

Under SBIR Phase I awards, generally, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried put by the small business concern (grantee). Furthermore, payments, in the aggregate, to consultants, consortium participants and contractors for portions of the scientific/technical effort generally may not exceed 33 percent of the total budget (direct and F&A (indirect) costs).

Under SBIR Phase II awards, generally, a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the small business concern (grantee). Furthermore, payments, in the aggregate, to consultants, consortium participants, and contractors for portions of the scientific/technical effort generally may not exceed 50 percent of the total budget (direct and F&A (indirect) costs).

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

Public Policy Requirements and Objectives

The requirements concerning disclosure of financial conflicts of interest (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Conflict of Interest") apply to Phase II SBIR/STTR awards only.

Allowability of Costs and Fee

Profit or Fee

A reasonable fixed fee may be paid to small business concerns receiving awards under Phases I and II of the SBIR and STTR programs. The fee is not considered a "cost" for purposes of determining allowability of use, program income accountability, or audit thresholds. The fee may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee is intended to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work; however, the amount of the fee approved will not normally exceed seven (7) percent of total costs (direct and F&A) for each phase of the project. The fixed fee applies solely to the small business concern (grantee) receiving the SBIR/STTR award and not to any other participant; however, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

Facilities and Administrative Costs (Indirect Costs)

Phase I

If the applicant small business concern has a currently effective indirect cost rate(s) with a Federal agency, such rates should be used when calculating proposed F&A costs. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant small business concern does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose estimated F&A costs at a rate not to exceed 40 percent of the total direct costs. However, small business concerns are reminded that only actual F&A costs are to be charged to projects. (If awarded at a rate of 40 percent or less, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the small business concern negotiates an indirect cost rate(s) with a Federal agency.)

Phase II

If the applicant small business concern has a currently effective negotiated indirect cost rate(s) with a Federal agency, such rate(s) should be used when calculating proposed F&A costs. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant small business concern does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose estimated F&A costs. If the small business concern is being considered for an award, it will be asked to submit detailed documentation if a rate in excess of 25 percent of total direct costs is requested. If the requested F&A cost rate is 25 percent or less, no further justification is required at the time of award, and F&A costs will be awarded at the requested rate. However, small business concerns are reminded that only actual F&A costs may be charged to projects. (If awarded at a rate of 25 percent or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the small business concern negotiates an indirect cost rate(s) with a Federal agency.)

Administrative Requirements

Market Research

NIH will not support market research, including studies of the literature that lead to a new or expanded statement of work, under the grant. For purposes of the SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the proposed research. It includes various types of research, such as the size of potential markets and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that require a survey of the public as part of the objective of the project to determine the impact of the subject of the research on the behavior of individuals.

Program Income

Unless the specific terms and conditions of an award provide otherwise, program income generated under SBIR/STTR Phase I and II awards shall be used under the additive alternative (see "Administrative Requirements—Management Systems and Procedures—Program Income" in Part II).

Intellectual Property: Rights in Data, and Inventions and Patents

Rights to data, including software developed under the terms of any funding agreement resulting from an NIH award, shall remain with the grantee except that any such copyrighted material shall be subject to a royalty-free, nonexclusive and irrevocable license to the Government to reproduce, publish or otherwise use the material, and to authorize others to do so for Federal purposes. In addition, under the SBIR/STTR programs, in contrast to awards to for-profit organi-

zations under other support mechanisms, such data shall not be released outside the Government without the grantee's permission for a period of 4 (four) years from completion of the project from which the data were generated.

The STTR program requires that the grantee organization (small business concern) and the single, "partnering" research institution execute an agreement allocating between the parties intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research. (For guidance, a model agreement, entitled "Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization," is included in the STTR Phase I grant solicitation and in the Phase II application package.) By signing the face page of the STTR grant application, the official signing for the applicant organization (small business concern) certifies that the agreement with the research institution will be effective at the time the grant award is made. A copy of the agreement must be furnished upon request of the NIH IC that issued the award.

SBIR/STTR grantees are covered by 37 CFR 401 with respect to inventions and patents, as provided above.

RESEARCH PATIENT CARE COSTS

General

This section provides NIH policy on the determination and reimbursement of research patient care costs under grants and cooperative agreements (hereafter "grants"). This general policy is intended to be applied in conjunction with the requirements of 45 CFR 74, Appendix E, Cost Principles for Determining Costs Applicable to Research and Development under Grants and Contracts to Hospitals. In addition, specific NIH programs may have additional or alternative requirements with which an applicant/grantee must comply. This includes the *General Clinical Research Center Guidelines* as specified below.

Definitions

Research Patient Care Costs are the costs of routine and ancillary services provided by hospitals to patients participating in research programs. The costs of these services are normally assigned to individual research projects through the development and application of research patient care rates or amounts (hereafter "rates"). Research patient care costs **do not include**: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of patients, including inpatients, outpatients, subjects, volunteers, and donors, and (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or in an affiliated medical school/university based on an institutional fee schedule, or (3) the data management or statistical analysis of clinical research results.

Hospital includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria.

Research Patients refers to inpatient and outpatient subjects, volunteers, or donors admitted to a hospital primarily to participate in a research protocol.

Routine Services are the regular room, dietary and nursing 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 are customarily made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology.

Outpatient Services are services rendered to subjects/volunteers who are not hospitalized.

Usual Patient Care refers to items and services (routine and ancillary) ordinarily furnished in the treatment of patients by providers of patient care under the supervision of the physician or other responsible health professional. Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional heath services. These expenses are for care that would have been incurred even if the research study did not exist. The patient and/or third-party insurance will usually provide for reimbursement of charges for "usual patient care" as opposed to non-reimbursement for those charges generated solely because of participation in a research protocol.

Discrete Centers are groups of beds that have been set aside for occupancy by research patients and are physically separated from other hospital beds in an environment that normally permits an ascertainable allocation of costs associated with the space they occupy and the service needs they generate.

Scatter Beds are beds assigned to research patients based on availability. These beds are not physically separate from non-research beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital and

are not usually distinguishable in terms of services or costs from other general service beds within the hospital.

Cost-Finding Process is the technique of apportioning or allocating the costs of the non-revenue-producing cost centers to each other and to the revenue-producing centers on the basis of the statistical data that measure the amount of service rendered by each center to other centers.

Policy

NIH provides funds for research patient care costs under grants. Research patients may receive routine services as inpatients or ancillary services as either inpatient or outpatient subjects/volunteers. In order to receive reimbursement for research patient care costs, any hospital that, as a direct recipient of NIH funds, will incur more than $100,000 in research patient care costs in any single budget period under an individual NIH or other HHS award must negotiate a research patient care rate agreement with the cognizant office of the HHS Division of Cost Allocation (DCA). These rates must be shown in all requests and/or claims for reimbursement of research patient care costs. Hospital grantees that will incur $100,000 or less in research patient care costs as calculated above and consortium participants/contractors under grants are subject to the requirements specified in the subsection below on "Special Procedures for Certain Hospitals." Failure to negotiate a research patient care rate with DCA, when required, may result in the disallowance of all research patient care costs charged to a grant.

Allowability of Costs

The determining factors for allowing research patient care costs as charges to NIH grants depend on the patient and the type of services received. If the patient is receiving service or care that neither differs from usual patient care nor results in expenses greater than those that would have been incurred if the study had not existed, then the patient is considered to be hospitalized for usual care purposes and the grant will not support the costs. When the research extends the period of hospitalization beyond that ordinarily required for usual care, or imposes procedures, tests or services beyond usual care, whether in an inpatient or outpatient setting, the grant may pay the additional costs. The grantee must decide whether, in fact, the hospitalization period, the tests, or the services have been extended beyond or added to what would ordinarily have been expected, and to what extent. Patient care costs for individuals who are receiving accepted treatment according to standard regimens would not ordinarily be acceptable charges to an NIH grant. Similarly, in certain kinds of clinical trials where accepted treatments are compared against new therapies, research patient care costs generally may be charged to a grant only insofar as they are measurements or services above and beyond those that constitute usual patient care and are specified by the study protocol.

NIH funds may be used to pay all costs (whether usual care costs or research care costs) for the entire period of hospitalization or research tests or services for patients who would not have been hospitalized or received such tests or services except for their participation in the research study. Any such exceptions should be documented in the grantee's records. These patients may include:

- Persons to whom no health advantages may be expected to accrue as a result of the hospitalization. Examples would be normal controls for metabolic or other studies; persons with genetic or certain abnormalities of interest to the investigator; and sick persons brought to the hospital solely for studies when they otherwise would not require hospitalization.

- Sick persons of research importance to the investigator but without funds of their own or without funds available to them through a responsible third party to pay hospitalization expenses. This includes patients for whom some third-party payer, such as city, county, or State government, might pay hospitali-

zation expenses in some other hospital but has no responsibility to pay in the hospital in which the approved clinical research is being conducted.

- Sick persons with limited personal funds or health insurance but who are not willing to spend their own money or use their hospital plan coverage at that particular time. (Fear of more urgent need in the future for both personal funds and health insurance might be one reason for the patient's reluctance to participate in the study.) The investigator has a special responsibility in making the decision to include patients in this group with full charges to the grant. Ordinarily, NIH expects the patient and/or third party to pay the total costs of the usual care portions of the hospitalization. However, in exceptional circumstances, the investigator may decide to pay the total expenses for hospitalization, research services, or tests from the grant if this is required to secure timely cooperation of a valuable study patient not otherwise available.

Computation of Research Patient Care Costs

Patient care costs, whether expressed as a rate or an amount, shall be computed in an amount consistent with the principles and procedures used by the Medicare program for determining the portion of Medicare reimbursement based on reasonable costs. Under this policy, separate cost centers must be established for each discrete bed unit for purposes of allocating or distributing allowable routine costs to the discrete unit.

When provisional rates are used as the basis for award of research patient care costs, the amount awarded shall constitute the maximum amount that the IC is obligated to reimburse the grantee for such costs. Provisional rates must be adjusted if a lower final rate is negotiated.

Facilities and Administrative Costs

F&A costs should not be paid on any cost component representing the cost of research patient care activities. Patient care rates (routine and ancillary) include F&A costs related to "hospital-type" employees (nurses, medical technicians, etc.) supported as a direct cost under a grant. Therefore, to preclude over-recoveries of costs similar to these F&A costs, salaries and wages (S&W) of all "hospital-type" employees working on the grant must be excluded from the S&W base used to claim F&A costs. Related fringe benefits should also be excluded if such costs are part of the S&W base. If a "total direct costs" base is used to compute and claim F&A costs, the above-mentioned "hospital-type" salaries must be excluded from the base also, as well as any other base costs chargeable to the grant through the application of a research patient care rate.

If the grant or a consortium agreement/contract under a grant provides funding exclusively for research patient care activities, no F&A costs will normally be allowed as a separate cost element since all allocable F&A costs will be accounted for in the routine or ancillary activity costs contained in research patient care rates.

Special Procedures for Certain Hospitals

Grantees

If a grantee does not meet the threshold for negotiation of a research patient care rate agreement with DCA in a given budget period, as specified under "Policy" in this section, but has a currently negotiated research patient care rate, that rate will be used in awarding and reimbursing research patient care costs, regardless of the amount. In all other cases, the hospital will be reimbursed at a rate not to exceed the lesser of actual research patient care costs or the rate included in the hospital's Medicare cost report.

Consortium Participants/Contractors Under Grants

If a hospital incurring research patient care costs is not the grantee, the grantee will be responsible for establishing the rate or amount that will be reimbursed for such costs unless the hospital is also a direct recipient of other HHS awards and in that capacity has established a rate with DCA.

If a participating hospital will incur more than $100,000 in research patient care costs (as specified for grantees in the "Policy" subsection), the grantee shall negotiate a rate for that hospital unless the relationship between the grantee and the hospital is considered "less-than-arms length." In this case, the grantee should contact the IC GMO to determine whether DCA will negotiate the rate.

If a participating hospital will incur $100,000 or less in research patient care costs, the grantee will use the lesser of actual costs or the rate in the hospital's Medicare cost report as the basis for determining reimbursement. For purposes of this paragraph, the grantee will apply the thresholds to each hospital individually.

Financial Responsibilities

Where the costs of patient care are funded by the grant, and whether such costs are classified as usual patient care or research patient care, the amount recovered from third parties must be credited to the grant. However, patient charges must be adjusted for both routine services and ancillaries prior to applying the third-party recoveries. The grantee is obligated to pursue recovery to the fullest extent possible and should be able to document those efforts. An example of such an adjustment follows:

If the standard fee schedule charge for a CT scan is $500, the negotiated research patient care agreement rate is 75 percent, and third-party insurance pays $300, the maximum amount that may be charged to the NIH grant is $75, based on the following calculation.

Standard Fee Schedule X (multiplied by) Negotiated Rate = Cost — (minus) Insurance = Maximum Charge to NIH Grant

$500 x .75 = $375 - $300 = $75

In those instances when the grantee determines that the balance of the patient's bill may be charged to the grant ("Allowability of Costs" in this section), the **total** bill must be adjusted to cost prior to applying any third-party recoveries. The remaining balance of allowable costs may then be charged to the grant.

In certain circumstances, funds may be awarded that support tests developed specifically for research purposes that are subsequently billed to third parties. In such cases, funds recovered from third parties must be credited to the grant account.

Program Requirements

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

Part IV: Points of Contact

Various offices/officials are mentioned throughout the preceding parts of this policy statement as sources of information or as responsible for certain activities in the NIH grants process. Contact information for these and other offices/officials is provided below. These addresses should not be used for express mail or other types of hand-deliveries. The IC should be contacted to obtain the street address and zip code.

For each IC that awards grants, a listing is provided for the Chief Grants Management Officer as well as an extramural program official that may be contacted for general information. The Web address for the IC's Home Page is also included. Requests related to particular applications submitted or grants awarded should be directed to the individual(s) specified in formal communications from NIH, e.g., in the Notice of Grant Award.

INSTITUTES AND CENTERS

<table>
<tr><th colspan="2">Fogarty International Center (FIC)
http://www.nih.gov/fic</th></tr>
<tr><td>Chief Grants Management Officer
Ms. Silver Mandes
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and Research
Building 31, Room B2C39, MSC 2220
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301/496-1653
301/402-0779 (fax)
e-mail: sm91g@NIH.GOV</td><td>Extramural Program Official
Dr. Kenneth Bridbord
Division of International Training
and Research
Building 31, Room B2C39, MSC 2220
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301/496-2516
301/402-2056 (fax)
e-mail: kb16n@NIH.GOV</td></tr>
<tr><th colspan="2">National Cancer Institute (NCI)
http://www.nci.nih.gov</th></tr>
<tr><td>Chief Grants Management Officer
Mr. Leo F. Buscher, Jr.
Executive Plaza South, Room 234, MSC 7150
Bethesda, MD 20892-7150
301/496-7753
301/402-3409 (fax)
e-mail: lb45u@NIH.GOV</td><td>Deputy Grants Management Officer
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<tr><td>Extramural Program Official
Dr. Marvin Kalt
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301/402-0956 (fax)
e-mail: mk74s@NIH.GOV</td><td></td></tr>
<tr><th colspan="2">National Center for Research Resources
http://www.ncrr.nih.gov</th></tr>
<tr><td>Chief Grants Management Officer
Ms. Joellen M. Harper
Director, Office of Grants Management
Rockledge I, Room 6086, MSC 7965
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301/435-0844
301/480-3777 (fax)
e-mail: jh41m@NIH.GOV</td><td>Extramural Program Official
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301/496-6023
301/402-0006 (fax)
e-mail: lr23m@NIH.GOV</td></tr>
</table>

National Eye Institute http://www.nei.nih.gov	
Chief Grants Management Officer Ms. Carolyn E. Grimes Chief, Extramural Services Branch Executive Plaza South, Room 350, MSC 7164 Bethesda, MD 20892-7164 301/496-5884 301/496-0528 (fax) e-mail: cg23w@NIH.GOV	Extramural Program Official Dr. Jack McLaughlin Executive Plaza South, Room 350, MSC 7164 Bethesda, MD 20892-7164 301/496-9110 301/402-0528 (fax) e-mail: jm82p@NIH.GOV
National Heart, Lung and Blood Institute (NHLBI) http://www.nhlbi.nih.gov/nhlbi/nhlbi.htm	
Chief Grants Management Officer Mr. William Darby Chief, Grants Operations Branch Rockledge II, Room 7128, MSC 7926 Bethesda, MD 20892-7926 301/435-0177 301/480-3310 (fax) e-mail: wd8u@NIH.GOV	Extramural Program Official Dr. Ronald Geller Rockledge II, Room 7100, MSC 7922 Bethesda, MD 20892-7922 301/435-0260 301/480-3460 (fax) e-mail: rg33k@NIH.GOV
National Human Genome Research Institute (NHGRI) http://nhgri.nih.gov	
Chief Grants Management Officer Ms. Jean M. Cahill Chief, Grants and Contracts Management Section Building 38A, Room 613, MSC 6050 Bethesda, MD 20892-6050 301/402-0733 301/402-1951 (fax) email: jc166o@NIH.GOV	Extramural Program Official Dr. Mark Guyer Building 38A, Room 604, MSC 6050 Bethesda, MD 20892-6050 301/402-5407 301/480-2770 (fax) e-mail: mg25m@NIH.GOV
National Institute on Aging (NIA) http://www.nih.gov/nia	
Chief Grants Management Officer Mr. Joseph Ellis Gateway Bldg., Room 2N212, MSC 9205 Bethesda, MD 20892-9205 301/496-1472 302/402-3672 (fax) e-mail: je14j@NIH.GOV	Extramural Program Official Dr. Miriam Kelty Gateway Bldg., Room 2C218F, MSC 9205 Bethesda, MD 20892-9205 301/496-9322 301/402-2945 (fax) e-mail: mk46u@NIH.GOV

National Institute on Alcohol Abuse and Alcoholism (NIAAA) http://www.niaaa.nih.gov	
Chief Grants Management Officer Ms Linda Hilley Chief, Grants Management Branch Willco Building, Suite 504, MSC 7003 Bethesda, MD 20892-7003 301/443-0915 301/443-8381 (fax) e-mail: lh76b@NIH.GOV	Extramural Program Official Dr. Kenneth Warren Parklawn Building, Room 409, MSC 7003 Bethesda, MD 20892-7003 301/443-4375 301/443-6077 (fax) e-mail: kw46m@NIH.GOV
National Institute of Allergy and Infectious Diseases (NIAID) http://www.niaid.nih.gov	
Chief Grants Management Officer Ms. Mary Kirker Grants Management Branch Solar Building, Room 4B21, MSC 7610 Bethesda, MD 20892-7610 301/402-6400 301/480-3780 (fax) e-mail: mk35h@NIH.GOV	Extramural Program Official Dr. John McGowan Solar Building, Room 3C20, MSC 7610 Bethesda, MD 20892-7610 301/496-7291 301/402-0369 (fax) e-mail: jm80c@NIH.GOV
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) http://www.nih.gov/niams	
Chief Grants Management Officer Ms. Sally A. Nichols Natcher Bldg., Room 5AS-49F, MSC 6500 Bethesda, MD 20892-6500 301/594-3535 310/480-5450 (fax) e-mail: sn21q@NIH.GOV	Extramural Program Official Dr. Steven Hausman Building 31, Room 4C32, MSC 2350 Bethesda, MD 20892-2350 301/402-1691 301/480-6069 (fax) e-mail: sh41g@NIH.GOV
National Institute of Child Health and Human Development (NICHD) http://www.nih.gov/nichd	
Chief Grants Management Officer Ms. Diane M. Watson Grants Management Branch 6100 Building, Room 8A01A, MSC 7510 Bethesda, MD 20892-7510 301/496-5001 301/402-0915 (fax) e-mail: dw40j@NIH.GOV	Extramural Program Official Dr. Yvonne Maddox Building 31, Room 2A03, MSC 2425 Bethesda, MD 20892-2425 301/496-1848 301/402-1104 (fax) e-mail: ym16x@NIH.GOV

National Institute on Deafness and Other Communication Disorders (NIDCD) http://www.nih.gov/nidcd	
Chief Grants Management Officer Ms. Sharon Hunt Chief, Grants Management Branch Executive Plaza South, Suite 400B, MSC 7180 Bethesda, MD 20892-7180 301/402-0909 301/402-1758 (fax) e-mail: sh79f@NIH.GOV	Extramural Program Official Dr. Craig Jordan Executive Plaza South, Suite 400C, MSC 7180 Bethesda, MD 20892-7180 301/496-8693 301/402-6250 (fax) e-mail: cj34b@NIH.GOV
National Institute of Dental Research (NIDR) http://www.nidr.nih.gov	
Chief Grants Management Officer Mr. Martin Rubinstein Natcher Bldg., Room 4AN-44A, MSC 6402 Bethesda, MD 20892-6402 301/594-4800 301/480-8301 (fax) e-mail: mr49c@NIH.GOV	Extramural Program Official Dr. Lois K. Cohen Natcher Bldg., Room 4AN-18E, MSC 6402 Bethesda, MD 20892-6402 301/594-7710 301/480-8319 (fax) e-mail: lc85n@NIH.GOV
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) http://www.niddk.nih.gov	
Chief Grants Management Officer Ms. Nancy Dixon Natcher Bldg., Room 6AS-49E, MSC 6600 Bethesda, MD 20892-6600 301/594-8842 301/480-3504 (fax) e-mail: nd11m@NIH.GOV	Extramural Program Official Dr. Walter Stolz Natcher Bldg., Room 6AS-25C, MSC 6600 Bethesada, MD 20892-6600 301/594-8834 301/480-3505 (fax) e-mail: ws23e@NIH.GOV
National Institute on Drug Abuse (NIDA) http://www.nida.nih.gov	
Chief Grants Management Officer Dr. Gary Fleming Parklawn Bldg., Room 8A-54, MSC 8001 Bethesda, MD 20892-8001 301/443-6710 301/594-6847 (fax) e-mail: gf6s@NIH.GOV	Extramural Program Official Dr. Teresa Levitin Parklawn Bldg., Room 10-42, MSC 8012 Bethesda, MD 20892-8012 301/443-2755 301/443-0538 (fax) e-mail: tl25u@NIH.GOV

National Institute of Environmental Health Sciences (NIEHS) http://www.niehs.nih.gov	
Chief Grants Management Officer Mr. David L. Mineo Chief, Grants Management Branch P.O. Box 12233 Research Triangle Park, NC 22709 919/541-1373 919/541-2860 (fax) e-mail: dm44x@NIH.GOV	Extramural Program Official Dr. Anne Sassaman P.O. Box 12233 Building 3, Room 301 Research. Triangle Park, NC 22709 Building 3 919/541-7723 919/541-2843 (fax) e-mail: as56j@NIH.GOV
National Institute of General Medical Sciences (NIGMS) http://www.nih.gov/nigms	
Chief Grants Management Officer Ms. Carol L. Tippery Natcher Bldg., Room 2AN-24C, MSC 6200 Bethesda, MD 20892-6200 301/594-5135 301/480-1969 (fax) e-mail: ct25i@NIH.GOV	Extramural Program Official Dr. Sue Shafer Natcher Bldg., Room 2AN-32D, MSC 6200 Bethesda, MD 20892-6200 301/594-4499 301/480-1852 (fax) e-mail: ss78v@NIH.GOV
National Institute of Mental Health (NIMH) http://www.nimh.nih.gov	
Chief Grants Management Officer Mr. Bruce L. Ringler Chief, Grants Management Branch Parklawn Bldg., Room 7C-08, MSC 8030 Bethesda, MD 20892-8030 301/443-3065 301/443-6885 (fax) e-mail: br10i@NIH.GOV	Extramural Program Official Dr. Richard Nakamura Parklawn Bldg., Room 17C-26, MSC 8030 Bethesda, MD 20892-8030 301/443-4335 301/443-3225 (fax) e-mail: rn3p@NIH.GOV
National Institute of Neurological Disorders and Stroke (NINDS) http://www.ninds.nih.gov	
Chief Grants Management Officer Mr. Ed Donohue Chief, Grants Management Branch Federal Building, Room 1004, MSC 9190 Bethesda, MD 20892-9190 301/496-4188 301/402-0219 (fax) e-mail: ed25b@NIH.GOV	Extramural Program Official Dr. Constance Atwell Federal Building, Room 1016, MSC 9190 Beethesda, MD 20892-9190 301/496-9248 301/402-4370 (fax) e-mail: ca23c@NIH.GOV

National Institute of Nursing Research (NINR) http://www.nih.gov/ninr	
Chief Grants Management Officer Mr. Jeff Carow Natcher Bldg., Room 3AN-32, MSC 6301 Bethesda, MD 20892-6301 301/594-6869 301/480-8256 (fax) e-mail: jc54d@NIH.GOV	Extramural Program Official Dr. Mary D. Leveck Natcher Bldg., Room 3AN-12, MSC 6300 Bethesda, MD 20892-6300 301/594-5963 301/480-8260 (fax) e-mail: ml118t@NIH.GOV
National Library of Medicine (NLM) http://www.nlm.nih.gov	
Chief Grants Management Officer Mr John Seachrist Division of Extramural Programs Rockledge I, Suite 301, MSC 7968 Bethesda, MD 20892-7968 301/594-4937 301/402-0421 (fax) e-mail: js132f@NIH.GOV	Extramural Program Official Dr. Milton Corn Rockledge I, Suite 301, MSC 7968 Bethesda, MD 20892-7968 301/496-4621 301/402-2952 (fax) e-mail: mc105x@NIH.GOV

OTHER NIH OFFICES

<table>
<tr><th colspan="2">Office of Extramural Research
Office of Policy for Extramural Research Administration (OPERA)
http://grants.nih.gov/grants/oer</th></tr>
<tr><td>Ms. Diana Jaeger
Director, Division of Grants Policy
Rockledge II, Room 2188, MSC 7730
Bethesda, MD 20892-7730
301/435-0932
301/435-3059 (fax)</td><td>Division of Extramural Outreach and Information Resources
Rockledge II, Suite 6095, MSC 7910
Bethesda, MD 20892-7910
301/435-0714
e-mail: grantsinfo@nih.gov</td></tr>
<tr><td>Inventions and Extramural Reporting Branch
Rockledge II, Room 3190, MSC 7750
Bethesda, MD 20892-7750
301/ 435-1986
301/480-0272 (fax)</td><td></td></tr>
<tr><th colspan="2">Office for Protection from Research Risks (OPRR)
http://grants.nih.gov/grants/oprr</th></tr>
<tr><td>For information concerning human subjects assurances:
Division of Human Subjects Protection Assurance Staff
6100 Executive Boulevard,Suite 3B01, MSC 7507
Bethesda, MD 20892-7507
301/496-7005

To obtain a copy of OPRR’s instructional videotape:
Education Program Coordinator
Division of Human Subjects Protection
Address and telephone number as above</td><td>For information concerning animal welfare assurances or to obtain a copy of the “Policy On Humane Care And Use Of Laboratory Animals”:

Division of Animal Welfare Assurance Staff
6100 Executive Boulevard, Suite 3B01, MSC 7507
Bethesda, MD 20892-7507
301/496-7163</td></tr>
<tr><th colspan="2">Center for Scientific Review (formerly the Division of Research Grants)
http://www.csr.nih.gov</th></tr>
<tr><td>Rockledge II, MSC 7776
Bethesda, MD 20892-7776

Referral Office 301/435-0715</td><td></td></tr>
</table>

Office of Recombinant DNA Activities http://www4.od.nih.gov/oba/	
6000 Executive Boulevard, Suite 302, MSC 7010 Bethesda, MD 20892-7010 301/496-9838	
Office of Financial Management http://www.nih.gov/od/ofm	
For grants paid by NIH and to register for electronic submission of Financial Status Reports: Government Accounting Branch Building 31, Room B1B05, MSC 2052 Bethesda, MD 20892-2052 301/402-9123	Hard-copy submission of Financial Status Reports: Building 31, Room B1B11 MSC 2052 Bethesda, MD 20892-2052 301/496-5287
Office of Contracts Management http://www.od.nih.gov/ocm	
Division of Financial Advisory Services 6100 Executive Boulevard, Room 6B05, MSC 7540 Bethesda, MD 20892-7540 301/496-4401	

OTHER HHS OFFICES

Office of the Inspector General (OIG)	
OIG Hotline http://www.oig.hhs.gov/hotline.html Attn: HOTLINE 330 Independence Avenue, SW Washington, DC 20201-800-HHS-TIPS (1-800-447-8477) e-mail: HHSTips@oig.hhs.gov	Questions concerning A-133 audit require-ments: National External Audit Resources Unit Office of Audit Services 323 West 8th Street Lucas Place, Room 514 Kansas City, Missouri 64105 800/732-0679 816/374-6714 (fax)
Office of Research Integrity http://ori.dhhs.gov	
5515 Security Lane, Rockwall II, Suite 700 Rockville, MD 20852 301/443-5300 301/594-0042 (fax)	
Departmental Appeals Board http://www.hhs.gov/dab	
330 Independence Avenue, SW Washington, DC 20201 202/690-5501 202/690-5863 (fax)	
Office for Civil Rights http://www.hhs.gov/progorg/ocr/ocrhmpg.html	
Office of Program Operations 200 Independence Avenue, SW Room 509 F Washington, DC 20201 202/619-0403	
Program Support Center **Financial Management Service** **Division of Payment Management** http://www.dpm.dhhs.gov	
P.O. Box 6021 Rockville, MD 20852 301/443-1660 301/443-3586 (fax) e-mail: info@psc.dhhs.gov	

Division of Cost Allocation	
Mid-Atlantic Field Office (Services Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia and West Virginia)	330 Independence Avenue, S.W. Room 1067 Washington, DC 20201 202/401-2808 202/619-3379 (fax)
Northeastern Field Office (Services Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Puerto Rico, the Virgin Islands, Canada and Europe)	26 Federal Plaza Room 41-122 New York, NY 10278 212/264-2069 202/264-5478 (fax)
Central States Field Office (Services Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, New Mexico, Ohio, Oklahoma, Texas and Wisconsin)	1301 Young Street Room 732 Dallas, TX 75202 214/767-3261 214/767-3264 (fax)
Western Field Office (Services Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, Australia, and Asia)	50 United Nations Plaza Room 304 San Francisco, CA 415/437-7820 415/437/7823

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[1] Entries are preceded by a "Part" designation; i.e., I, II, or III, pertaining to all pages within that part rather than being repeated; for example, I-2; II-45, 46, 70; III-5.

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