FOGARTY INTERNATIONAL CENTER

GRANTS INFORMATION RESOURCE PACKAGE

INDEX

GLOSSARY OF COMMONLY USED TERMS

Section 1

Part I: NIH Grants—General Information

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 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 Organizational Official: The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards.

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 intervals of time (usually 12 months each) 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 a competing continuation award 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.

Consultant: An individual that provides professional advice or services on the basis of a written agreement for a fee. These individuals are not normally employees of the organization receiving the services. Consultants also include firms that provide professional advice 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.

Co-Investigator: An individual involved with the principal investigator in the scientific development or execution of a project. The co-investigator may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the principal investigator's roles and responsibilities as specified in this policy statement.

Cost Sharing: See "Matching or Cost Sharing."

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

Domestic Organization: A public or private non-profit institution (including Federal, State, and other agencies) or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.

Equipment: An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds the lesser of the capitalization 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.

Fee: An amount in addition to actual, allowable costs incurred that is normally paid to a for-profit organization under a contractual arrangement. This increment above cost also is referred to as "profit." (Also see "Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowability of Costs and Fee—Profit or Fee.")

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

Foreign Component: Under a grant to a domestic organization, 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 organization, with or without grant funds.

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 also are referred to as "commercial organizations."

Full-Time Appointment: The number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH Institute or Center 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 permit 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.

Hospital: A non-profit or for-profit hospital or medical care provider component of a non-profit organization (for example, a foundation). The term includes all types of medical, psychiatric and dental facilities, such as clinics, infirmaries, and sanatoria.

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 terms "NIH IC" or "awarding office" are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award. In the latter case, the terms refer specifically to the designated Grants Management Officer.**

Institutional Base Salary: The annual compensation paid by an applicant/grantee organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

International Organization: An organization that identifies itself as international or intergovernmental, and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.

Key Personnel: 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 and collaborators are 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.

Modular Application: A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

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.

New Investigator: An individual that has not previously served as a principal investigator on any Public Health Service-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory development grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research careers ((K01, K08, and K12). Current or past recipients of Independent Scientist and other non-mentored career awards (K02 and K04) are not considered "new investigators."

Notice of Grant Award: The legally binding document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.

Organization: A generic term used to refer to an educational institution or other entity, including an individual, which 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 designated 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 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."

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Significant Rebudgeting: A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.

Small Business Concern: A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the 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 generally are 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 pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

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 post-award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Total Project Costs: The total allowable costs (both direct costs and 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
OHRP	Office for Human Research Protections
OIG	Office of the Inspector General
OLAW	Office of Laboratory Animal Welfare
OMB	Office of Management and Budget
OPERA	Office of Policy for Extramural Research Administration
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

GENERAL GRANTS INFORMATION

TO ASSIST NEW GRANTEES

Section 2

NIH "WELCOME WAGON" LETTER

Information for New Grantee Organizations

Updated: 7/17/2001

Information provided is primarily for officials of organizations planning to submit a grant or cooperative agreement (hereinafter referred to as grant) application or receiving an award from the National Institutes of Health (NIH) for the first time. The intent is to highlight key requirements, provide referrals to important sources of information, and identify NIH, Public Health Service (PHS) and Department of Health and Human Services (HHS) offices that have responsibility for certain administrative functions. Information available through these resources is important to those having responsibility for the administrative and fiscal management of NIH grant awards.

This letter may also be helpful to established grantee organizations because it updates previous issues and cites new and current provisions.

While the "Welcome Wagon" letter (http://grants.nih.gov/grants/funding/welcomewagon.htm) highlights or summarizes important issues, it is neither intended to nor does it serve as a substitute for the NIHGPS.

REQUIREMENTS AND PROVISIONS

Terms of Award

Acceptance of a grant award from NIH carries with it the responsibility to be aware of and comply with the terms and conditions of award. The Notice of Grant Award (NGA) states:

> This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:
>
> a. The grant program legislation and program regulation cited in this Notice of Grant Award.
>
> b. The restrictions on the expenditure of Federal funds in appropriation acts, to the extent those restrictions are pertinent to the award.
>
> c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
>
> d. The National Institutes of Health Grants Policy Statement is in effect as of the beginning date of the budget period.
>
> e. This award notice including any special terms and conditions.

The National Institutes of Health Grants Policy Statement

The National Institutes of Health Grants Policy Statement (NIHGPS), revised and issued in March of 2001, is a "term and condition" for all NIH assistance awards with budget periods beginning on or after 03/01/01. The contents of the document are legally binding requirements

for all grant recipients. In accepting a grant, recipients agree to comply with all provisions and requirements contained in the NIHGPS. The previous edition (10/01/98) is in effect for budget periods that began before 3/1/2001.

The NIH GPS covers policy topics such as modular applications, SNAP procedures (streamlined non-competing application process), prior approval authorities, and awards to foreign entities, etc. A search mechanism is provided to facilitate easy access to information.

If you do not have a copy of the NIHGPS, you may access an HTML version at http://grants.nih.gov/grants/policy/policy.htm. If you do not have access to the NIH Homepage, a copy of the NIHGPS may be obtained by sending an e-mail request to grantsinfo@nih.gov or by calling GRANTSINFO at (301) 435-0714.

45 CFR Part 74 and 45 CFR Part 92

Regulations found at Title 45, Code of Federal Regulations (CFR), Parts 74 and 92, are the HHS rules and requirements that govern the administration of grants. Part 74 is applicable to all recipients except those covered by Part 92, which governs awards to state and local governments. As is the case for the NIH Grants Policy Statement, these regulations are a term and condition of award. Grant recipients must be aware of and comply with the regulations. The CFR volume that includes Parts 74 and 92 may be ordered from:

U.S. Government Printing Office
Superintendent of Documents
Mail Stop SSOP
Washington, D.C. 20402-9328

The 45 CFR Parts 74 and 92 may also be accessed from HHS GrantsNet at:

http://www.hhs.gov/grantsnet/

Reporting Requirements

- Financial Status Report (FSR): The FSR is submitted on Standard Form 269 (Long Form) or Standard form 269A (Short Form) as the report of expenditures documenting the financial status of the award, according to the official accounting records of the grantee organization.

The FSR for each budget period must be submitted within 90 days after the close of the budget period (see NIHGPS), unless the grant was awarded under the streamlined non-competing award process (SNAP). FSRs for grants subject to SNAP are due 90 days after the close of the competitive segment (see NIHGPS). When reporting grant-related program income, the long-form FSR (SF 269) must be used. (See NIHGPS for a further explanation of grant-related program income).

FSRs submitted to the NIH are submitted to the NIH Office of Financial Management for review and acceptance. They are then forwarded to the awarding office for review and inclusion in the official grant file. FSRs for other PHS components other than NIH should be submitted directly to the Grants Management Officer of the PHS component that made the award.

FSRs for NIH awards should be sent to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
31 Center Drive, Room B1B05A, MSC 2050
Bethesda, MD 20892-2050
Tel: (301) 402-9123

NIH has a system for the electronic transmittal of FSRs that allows participants to list currently due and late FSRs as well as to submit FSRs electronically. To register to use this system, contact the Government Accounting Branch at (301) 402-9123.

- Progress Report: All NIH assistance awards require, at a minimum, an annual progress report, which is usually submitted with the application for continuation support (PHS Form 2590). Refer to the competing or non-competing PHS application forms for the appropriate instructions. If an application will not be submitted because continuation support is not desired, a final progress report must be submitted within 90 days after the expiration or termination of the project (see NIHGPS).

- Inventions Report: Grantees retain the rights to patentable inventions that were conceived or reduced to practice during the course of an NIH grant award. In accepting an award, the grantee agrees to comply with the Government-wide patent regulations found at Title 37, Code of Federal Regulations (CFR) Part 401. (See NIHGPS.) In addition, the invention must be reported in continuation applications (competing or non-competing). Moreover, the invention must be included on the Final Invention Statement and Certification (HHS 568), which is required within 90 days following the expiration or termination of the project. (See NIHGPS.) A downloadable version of the HHS 568 is available at: http://grants.nih.gov/grants/forms.htm#inventionstatement. All invention reporting information should be sent to the following address or via IEdison:

  The Extramural Inventions and Technology Resources Branch
  Office of Policy for Extramural Research Administration, OER, NIH
  6705 Rockledge Drive, MSC 7980
  Bethesda, MD 20892-7980
  TEL: (301) 435-1986

  e-mail: edison@od.nih.gov Website for IEdison: http://www.iedison.gov

Audit Requirements

Audit requirements for Federal award recipients are defined in OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations (revised June 24, 1997). 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). 45CFR 74.26(d) provides for-profit organizations with 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. 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.

OMB Circular A-133 now requires auditees to submit a completed data collection form (SF-SAC) with the audit reporting package to the Federal clearinghouse designated by OMB – currently the Federal Audit Clearinghouse, Bureau of the Census, 1201 E. 10th Street, Jeffersonville, IN 47132. For questions concerning the submission process or to obtain a copy of the form, you may call the Federal Audit Clearinghouse (888-222-9907). Information can also be found on the Internet at http://harvester.census.gov/sac/. The data collection form is not required for audits of for-profit organizations. Audit reports of for-profit organizations should be submitted to the National External Audit Review Center, HHS Office of Audit Services, Lucas Place Room 514, 323 West 8th Street, Kansas City, MO 64105.

Additional detailed information relating to audit requirements for commercial/for-profit organizations is available at http://ocm.od.nih.gov/dfas/faqforprofitaudits.htm.

Protection of Human Subjects in Research

Every applicant is required to provide a written Assurance of Compliance with regulations pertaining to the protection of human subjects in research (45 CFR Part 46). No award involving human subjects will be made unless DHHS has approved an Assurance of Compliance for the grantee involving human subjects. If there are collaborating sites, it is the grantee's responsibility to ensure that human subject assurances are in place with collaborators prior to the start of human subject activity. In addition, the grantee must provide certification 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. In addition, there is for the protection of human participants.

Instructions are provided for the Federal Wide Assurance. Certification of IRB review is under "just-in-time" procedures.

Additional information is available regarding Conflict of Interest, Financial Conflict of Interest and Data Safety and Monitoring for clinical trials, Required Education for the protection of human research participants including Women, Minorities & Children. Also, The URL for "Protecting Human Research Subjects: Institutional Review Board Guidebook" is: http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm. To obtain information concerning a human subject assurance, contact OHRP at:

Office for Human Research Protections
Department of Health and Human Services
6100 Executive Boulevard, Suite 3B01, MSC-7507
Rockville, MD 20892-7507
301 496-7005
e-mail address: ohrp@od.nih.gov

To assist institutional review board (IRB) members, researchers, and institutional administrators, OHRP (formerly OPRR) produced a 1993 publication entitled, Protecting Human Research Subjects: Institutional Review Board Guidebook. It is available for $31 from the U.S. Government Printing Office at (202) 512-1800; stock no. 017-040-00525-3.

In addition, OHRP provides an instructional videotape on the Protection of Human Subjects. This videotape, available free of charge, contains three components:

- Evolving Concern, Protection for Human Subjects
- Balancing Society's Mandates, IRB Review Criteria
- The Belmont Report, Basic Ethical Principles and Their Application

To obtain a copy of the videotape, contact:

Education Program Coordinator
Division of Human Subjects Protection
OHRP, OER, NIH
6100 Executive Boulevard, MSC 7507
Suite 3B01
Rockville, MD 20892-7507
TEL: (301) 496-7005

Care and Use of Laboratory Animals in Research

The Public Health Service Policy on Humane Care and Use of Laboratory Animals governs the use of all live vertebrate animals in research supported by the NIH. This policy provides for humane treatment and care of animal research subjects. No award involving the use of animals will be made unless the NIH Office of Laboratory Animal Welfare has approved an Animal Welfare Assurance. To obtain information regarding animal welfare assurance requirements or to request a copy of the Public Health Service Policy on Humane Care and Use of Laboratory Animals, contact:

Office of Laboratory Animal Welfare
Rockledge 1, Suite 1050, MSC 7982
6705 Rockledge Drive Bethesda, MD 20892-7982
TEL: (301) 496-7163 FAX: (301) 402-2803 or 7065

Web page: http://grants.nih.gov/grants/olaw/olaw.htm

e-mail address: olaw@od.nih.gov

Biotechnology Activities

Organizations planning to conduct research involving recombinant DNA technology are required to establish a standing Biosafety Committee. The requirements for the composition of a committee of this type are published in the NIH Guidelines for Research Involving Recombinant DNA Molecules and Gene Transfer. This information may be obtained from:

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MD 20892
Tel: (301) 496-9838
Fax: (301) 496-9839

e-mail address: oba@nih.gov

Office of Research Integrity

The DHHS Office of Research Integrity (ORI) is responsible for implementing the assurance system related to procedures on scientific misconduct. An organization receiving NIH grant support for research is required to certify compliance with CFR 42 Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with Possible Misconduct in Science", as part of the grant application. ORI also requires an annual report (Form 6349) detailing aggregate information on allegations, inquiries and investigations that were handled by a grantee organization. The annual report forms constitute the organizational official's assurance to ORI that the organization has established internal policies and procedures and will comply with PHS regulations for reviewing, investigating and reporting allegations of misconduct in science conducted at, or sponsored by, the organization.

To obtain the above referenced forms, or for additional information regarding scientific misconduct and research integrity, contact:

Office of Research Integrity
Assurance Program
5515 Security Lane
Rockville, MD 20852
TEL: (301) 443-5300
FAX: (301) 594-0042

Public Policy Requirements

Applicants, upon signing an application requesting Federal assistance, certify compliance with a number of public policy requirements, some of which are established in or flow down from legislative or regulatory provisions. These policies govern such areas as objectivity in research, civil rights, environmental impact, biosafety, drug-free workplace, debarment and suspension, Federal debt, and lobbying with Federal funds and are intended to ensure fairness, equity, and physical and other protections in activities which receive PHS financial assistance. The public policy requirements and objectives governing NIH awards are presented in the NIHGPS.

Public policy requirements concerning civil rights, handicapped individuals, sex discrimination, and age discrimination require the one-time submission of Assurance Form HHS 690 prior to award and certification in all subsequent applications that the form (or the previous forms HHS 441, 641, 639-A, and 680) has been filed.

To obtain the forms, send an email to grantsinfo@nih.gov or call GRANTSINFO at (301) 435-0714.

To inquire as to whether your organization has previously filed the HHS 690 or the previous forms, contact the DHHS Office for Civil Rights at (202) 619-0403.

COST PRINCIPLES

The costs of a grant-supported activity are comprised of allowable direct costs, plus the allocable portion of the organization's associated facilities and administrative (F&A) costs. Direct costs are costs that can be specifically identified with a particular project or program, while F&A costs are incurred for common or joint objectives and which therefore cannot be identified specifically with a particular project or program. The allowability, allocability, reasonableness and necessity of direct and F&A costs that may be charged to NIH grants are outlined in five sets of cost principles.

OMB Circular A-21	Institutions of Higher Education
OMB Circular A-87	State and Local Governments
OMB Circular A-122	Nonprofit Organizations
45 CFR Part 74, Appendix E	Hospitals
FAR 48 Subpart 31.2	For-profit Organizations

Facilities & Administrative Cost Rate Negotiations

The payment of facilities & administrative (F&A) costs is based upon rates established through a formal agreement between the grantee organization and the cognizant Federal agency. The negotiated rate is applied to the direct cost base for individual grants to determine the amount of costs to be awarded. HHS/NIH recognizes F&A cost rates applicable to research activities negotiated by other Federal agencies adjusted for the HHS treatment of independent (self-sponsored) research and development (IR&D) costs. NIH does not reimburse F&A costs on grants to individuals, or agencies of the Federal Government, or on construction and conference grants. F&A is provided to foreign grantees beginning with FY 2002 based on a rate of 8%.

F&A rates are not negotiated for Phase I SBIR/STTR awards.

ADMINISTRATIVE STANDARDS FOR GRANTS

In addition to the cost principles, OMB has established administrative standards and audit requirements for organizations receiving Federal assistance.

OMB Circular A-102	State and Local Governments and Indian Tribes

OMB Circular A-110 Higher Education, Hospitals, and Other Nonprofit Organizations

OMB Circular A-133 Audits of States, Local Governments, and Non-Profit Organization

- The OMB website is: http://www.whitehouse.gov/OMB/.
- Copies of the Office of Management and Budget (OMB) Circulars are available on the Internet at: http://www.whitehouse.gov/OMB/circulars/ or by calling (202) 395-7332.
- The Federal Acquisition Regulations (FAR) Part 31 contains contract cost principles and procedures applicable to for-profit organizations and may be obtained from the Internet at: http://www.arnet.gov/far/

ELECTRONIC RESEARCH ADMINISTRATION

The Electronic Research Administration (eRA) Commons is a virtual meeting place where NIH extramural grantee organizations, grantees, and the public can receive and transmit information about the administration of biomedical and behavioral research. The ERA Commons is divided into both unrestricted and restricted portions that provide for public and confidential information, respectively. For more information, user support, and access to the web site, go to: http://era.nih.gov/. The email address is: commons@od.nih.gov.

Electronic Access to Grant-Related Resources over the Internet

Anyone with an Internet connection can electronically access numerous grant-related resources such as the NIHGPS, NIH Guide for Grants and Contracts, NIH Telephone Book and other grant resources at the following Internet address:

- http://grants.nih.gov/grants/oer.htm

This address can be reached through software clients such as Netscape or other browsers for World Wide Web (www) servers. The over 20 NIH Institutes and Centers have also established home pages on the www.

If you have problems in connecting electronically, contact your local Internet service provider.

NIH Guide For Grants and Contracts

The NIH Guide for Grants and Contracts (NIH Guide), published daily and indexed weekly, provides information to the research community regarding NIH Program Announcements (PAs), Requests for Applications (RFAs), Requests for (contract) Proposals (RFPs), and Notices of NIH Policy. The NIH Guide is available at http://grants.nih.gov/grants/oer.htm.

NIH Extramural Research and Research Training Programs

A wealth of information about NIH programs and funding opportunities is available on the NIH homepage http://grants.nih.gov/grants/funding/funding.htm. Applicants and grantees without access to the Internet may request a list of publications by calling GRANTSINFO at (301) 435-

0714.

Electronic Notification of Grant Award

NIH can transmit electronic Notices of Grant Award (e-NGA) to all NIH grant and cooperative agreement recipients capable of receiving e-NGAs. All of the information included in a paper NGA is provided in an e-NGA. Detailed instructions to obtain e-NGAs may be found at http://grants.nih.gov/grants/guide/notice-files/not98-129.html.

NIH Award Data

Data about NIH awards are available on the NIH web site (http://www.nih.gov), under "Grants and Contracts," "Grants Page," "Award Data." These data include:

CRISP (Computer Retrieval of Information on Scientific Projects)
NIH Awards by Congressional District
NIH Awards by State
Research Grants & Contracts (The Brown Book)
NIH Extramural Data and Trends
Recent Awards by Institute and State

NIH GRANT APPLICATION INSTRUCTIONS AND FORMS

Details concerning application procedures, application forms, and dates for submission of applications may be obtained electronically by e-mail from grantsinfo@nih.gov. Activity (mechanisms) codes, organization codes, and definitions used in extramural programs can be found at http://grants.nih.gov/grants/funding/ac.pdf.

Application forms used for the majority of the NIH grant programs are listed below.

PHS 398 Application for Public Health Service Grant (including Research Career Development Awards and Institutional National Research Service Awards): this form is used for new, competing continuation, and supplemental applications.

PHS 2590 Application for Continuation of a Public Health Service Grant (including Research Career Development Awards and Institutional National Research Service Awards): this form is used for non-competing continuation applications.

PHS 416-1 Application for Public Health Service Individual National Research Service Award (Fellowship)

PHS 416-9 Application for Public Health Service Individual National Research Service Award (Fellowship) Continuation.

SF 424 Application for Federal Assistance: used for construction programs only

PHS 5161-1 Application for Federal Assistance Non-Construction Programs (State and Local Government applicants only)

The PHS 398 and PHS 2590 instructions (HTML) and forms in Adobe Acrobat are available on the NIH web site (http://www.nih.gov), under "Grants and Funding Opportunities," "Grants page." If you do not have access to the Internet, you may order the forms by calling GRANTSINFO at (301) 435-0714 or sending an e-mail to grantsinfo@nih.gov.

The NIH will mail (fourth class) application materials to institutional offices of sponsored research (or equivalent) upon request. Requests should be for the anticipated number needed for six to twelve months. Requests should be made by sending e-mail to: grantsinfo@nih.gov or by calling GRANTSINFO at (301) 435-0714.

OTHER IMPORTANT OFFICES AT NIH AND HHS

Payment Procedures

Payments for grants awarded by NIH are made through the Division of Payment Management with the exception of awards to individuals, foreign organizations, and agencies of the Federal Government, which are paid by the NIH Office of Financial Management. Applicant organizations are assigned a 12-digit Entity Identification Number for payment and accounting purposes. That number is an expansion of the 9-digit Employer Identification Number assigned to an organization by the Internal Revenue Service.

The Payment Management System is administered by the Program Support Center (PSC),

DHHS. Requests for downloadable forms and inquiries regarding payments should be directed to:

Division of Payment Management
P.O. Box 6021
Rockville, MD 20852
(301) 443-1660

Questions regarding payments of grants to individuals, foreign organizations, and agencies of the Federal Government should be addressed to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
31 Center Drive, Room B1B05A, MSC 2050
Bethesda, MD 20892-2050
Tel: (301) 402-9123

Patient Care Costs

In instances where the proposed project represents a clinical research study, funds may be requested in a grant application for Patient Care Costs. Due to the special nature of these costs, a detailed explanation is required in the application as to how the total amount requested was determined. In situations where the amount requested for patient care results in an award that exceeds $100,000 in that category for a single budget period, the grantee organization must either have in place or take steps to develop a negotiated patient care rate agreement with HHS.

Hospitals and nonprofit organizations with questions concerning the negotiation of F&A cost rate agreements or patient care rate agreements should contact the appropriate office listed below.

HHS DIVISION OF COST ALLOCATION REGIONAL OFFICES

Region/Address for Grantees Located In:	
Northeast 26 Federal Plaza Room 41-118 New York, NY 10278 (212) 264-2069	Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Puerto Rico, Virgin Islands
Mid-Atlantic HHS Building, Room 5130 330 Independence Ave., S.W. Washington, DC 20201 (202) 401-2814	Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky Maryland, Mississippi, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia, West Virginia
Central States 1200 Main Tower Building	Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana,

Room 1135 Dallas, TX 75202 (214) 767-3261	Michigan, Minnesota, Missouri, Nebraska, New Mexico, Ohio, Oklahoma, Texas, Wisconsin
Western 50 United Nations Plaza Room 304 San Francisco, CA 94102 (415) 437-7820	Alaska, Arizona, California Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming

For-profit organizations should contact:

Office of Acquisition Management and Policy, NIH
6100 Executive Boulevard, Room 6B05, MSC 7540
Bethesda, MD 20982-7540
(301) 496-4401

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

EXCERPT FROM
GRANTS POLICY STATEMENT
(Pages 239—242)

Section 3

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

General

Most of the policies contained in Subpart A of this part apply to NIH grants made to foreign institutions and international organizations (hereafter "foreign grants"), including the requirements of 45 CFR Part 74 or 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 in this section. This section also includes policies that apply to domestic grants with a 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 foreign component. For purposes of this policy, a "foreign component" is defined as performance of any significant element or segment of the project outside the 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 "foreign component."

See "Support of Scientific Meetings (Conference Grants)" 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 objectives of the 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

A complete listing of public policy requirements and objectives and their applicability to foreign grants is contained in Table II-1. Several of the public policy requirements and objectives are highlighted in this subsection.

Research Misconduct. This public policy requirement 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 consortium participants under domestic or foreign grants also 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 women, members of minority groups, and children in research design as specified in "Public Policy Requirements and Objectives—Requirements for Inclusiveness in Research Design."

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

Lobbying. The requirements of "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying," including disclosure reporting, apply to foreign grants.

Debt. Foreign applicants are required to provide a certification of 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 subject to the certification requirement concerning suspension or debarment nor 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 IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government.

Funding and Payment

The application budget, requests for funds, and financial reports (see "Reporting and Record Retention" in this section) 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 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 III for address and telephone and fax numbers).

Allowability of Costs/Activities

The costs that are generally allowable under grants to domestic organizations also are 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

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 scope and requires NIH prior approval. The transfer of work by a domestic grantee to a foreign component always requires NIH prior approval even if it does not constitute a change in scope.

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

Reporting and Record Retention

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

F&A COSTS FOR FOREIGN AND INTERNATIONAL ORGANIZATIONS

Section 4

3/1/01 NIH Policy Statement section : *Awards to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components* and the *Allowability of F&A Costs for Foreign and International Organizations.*

Please click here to go to the Foreign section/chapter of the NIH Policy Statement.

Please be aware that the NIH policy concerning the allowablility of F&A costs for Foreign and International Organizations has changed. An excerpt from the March 29, 2001 NIH Guide for Grants and Contracts Announcement titled : ALLOWABILITY OF FACILITIES AND ADMINISTRATIVE (F&A) COSTS FOR FOREIGN AND INTERNATIONAL ORGANIZATIONS is provided below.

ALLOWABILITY OF FACILITIES AND ADMINISTRATIVE (F&A) COSTS FOR FOREIGN AND INTERNATIONAL ORGANIZATIONS Release Date: March 29, 2001
NOTICE: NOT-OD-01-028

National Institutes of Health

In the past, Department of Health and Human Services (DHHS) policy prohibited the provision of facilities & administrative (F&A) costs on foreign and international awards. As a result, the National Institutes of Health (NIH) and the extramural community have had concerns that by not providing some allowance for F&A costs to these organizations, valuable research opportunities may be lost.

Effective October 2001 (FY 2002), NIH will provide limited F&A costs to foreign and international organizations. The provision of F&A costs to foreign and international organizations is to support the costs of compliance with DHHS and NIH requirements including but not limited to, the protection of human subjects, the welfare of animals, financial conflict of interest, and invention reporting.

This implementation will affect new and competing continuation awards. Established commitment levels on non-competing continuation awards will not be adjusted; however, funds may be rebudgeted to cover these costs. **The F&A costs should be requested in competing applications and may not exceed eight percent of total direct costs less equipment.** Also, domestic organizations that submit applications with a foreign or international consortium may request eight percent of total direct costs less equipment, for the consortium. **NIH will not support the acquisition of, or provide for depreciation on any capital expenses (facilities), or normal general operations related to foreign and**

international organizations.

Please click here to go to the see the complete F&A guide announcement.

Additional questions regarding the implementation of F&A costs to foreign and international organizations may be directed to the NIH Division of Grants Policy at (301) 435-0949 or the Grants Management Specialist identified on the NIH Notice of Grant Award.

We welcome your questions and comments about FIC and its research programs. Please send e-mail inquiries to the **Office of Communications.** Telephone: 301-496-2075 Fax: 301-594-1211.

TOP

Office of Communications • Fogarty International Center • National Institutes of Health
Building 31, Room B2C29 • 31 CENTER DR MSC 2220
Bethesda, MD 20892-2220

ALLOWABILITY OF FACILITIES AND ADMINISTRATIVE (F&A) COSTS FOR FOREIGN AND INTERNATIONAL ORGANIZATIONS

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Affected applicants that have already submitted applications request these costs at the time any potential award is negotiated.

INQUIRIES

Additional questions regarding the implementation of F&A costs to foreign and international organizations may be directed to the NIH Division of Grants Policy at (301) 435-0949 or the Grants Management Specialist identified on the NIH Notice of Grant Award.

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ALLOWABLE COSTS/ACTIVITIES

Excerpt From the
NIH Grants Policy Statement
(Pages 88-104)

(This List is Not All-inclusive)

Section 5

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

Allowability of Costs/Activities

The governing cost principles address selected items of cost, some of which are mentioned in this subsection for emphasis. The cost principles themselves should be consulted for the complete explanation of the 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 designated 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 type of 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") 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, as applicable. Individual A&R projects exceeding $500,000 will be subject to the requirements specified in the "Construction Grants" section.

Routine maintenance and repair of the organization's physical plant or its equipment, which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this NIH 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 purpose 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 result in a change in scope. If the rebudgeting results in an A&R project exceeding $300,000, NIH will consider the rebudgeting to be a change in scope, and the grantee must submit to the NIH IC the documentation specified in "Construction Grants" for approval of A&R projects above that dollar level.

Animals: Allowable for the acquisition, care, and use of experimental animals. If the grantee operates an animal resource facility, charges for use of the facility should be determined in accordance with the *Cost Analysis and Rate Setting Manual for Animal Resource Facilities* (May 2000), available from the National Center for Research Resources (NCRR) at its Web site: (http://www.ncrr.nih.gov/newspub/CARS.pdf) or from the NCRR Office of Science Policy and Public Liaison, 6705 Rockledge Drive, Bethesda, MD 20892-7965, (301) 435-0888, e-mail: ospio@ncrr.nih.gov.

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 proportional basis, and this practice is followed consistently by the grantee. Otherwise, charges for audits should be treated as F&A costs.

Bad Debts: Unallowable.

Bid and Proposal Costs: Allowable as an F&A cost. See 45 CFR 74.27(b)(1) for policy for nonprofit 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 also may be charged to the grant. (Also see "Construction Grants—Allowability of Costs/Activities.")

Child Care Costs: Allowable if incurred to assist individuals to participate as subjects in research projects. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see "Fringe Benefits" in this subsection).

Communications: Allowable. Such costs include local and long-distance telephone calls, telephone surveys, telegrams, and postage, and are usually treated as F&A costs.

Conference Grant Costs: See "Support of Scientific Meetings (Conference Grants)" 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 "Consortium Agreements" for policies that apply to grantee collaboration with other organizations in carrying out the grant-supported research.)

Construction: Allowable only when program legislation specifically authorizes new construction, modernization, or major A&R, and NIH specifically authorizes such costs in the NGA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy (see "Construction Grants").

Consultant Services: Allowable. A consultant is an individual retained to provide professional advice or services on a project for a fee but usually not as an employee of the requiring organization. The term "consultant" also includes a firm that provides paid professional advice or services. Grantees must have written policies governing their use of consultants that are consistently applied regardless of the source of support. The general circumstances of allowability of these costs, which may include fees and travel and subsistence costs, are addressed in the applicable cost principles under "professional services costs."

In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee as long as those separate services are not related to the same project and are not charged to the same project. 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. **Under no circumstances can an individual be paid as a consultant and an employee under the same NIH grant.**

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" 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 non-construction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see "Reserve Funds" in this subsection). (See "Construction Grants—Allowability of Costs/Activities—Allowable Costs/Activities" 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 "Awards to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components—Allowability of Costs/Activities" for the allowability of these costs under awards to those types of organizations.)

Depreciation or Use Allowances: Allowable. Such costs are usually treated as F&A costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable.

Donor Costs: Allowable for payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related.

Drugs: Allowable if within the scope of an approved research project.

Project funds may not be used to purchase drugs classified by 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 organizational policy consistently applied regardless of the source of funds.

Entertainment Costs: Unallowable. This includes the cost of amusements, social activities, and related incidental costs.

Equipment: Allowable for purchase of new, used, or replacement equipment as a direct cost or as part of F&A costs, depending on the intended use of the equipment. NIH prior approval may be required as specified in "Administrative Requirements—Changes in Project and Budget."

In accordance with the requirements of NIH appropriations acts, American-made items should be purchased to the extent possible.

Funds provided under a conference grant may not be used 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 "Grants to Federal Institutions and Payments to (or on Behalf of) Federal Employees Under Grants—Allowability of Costs/Activities" 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 NIH IC.

Fringe Benefits: Allowable as part of overall compensation to employees in proportion to the amount of time or effort employees devote to the grant-supported project, provided such costs are incurred under formally established and consistently applied policies of the organization (see "Salaries and Wages" in this subsection).

Tuition or tuition remission for regular employees is allowable as a fringe benefit. For organizations subject to OMB Circular A-21, tuition benefits for family members other than the employee are unallowable. For policies applicable to tuition remission for students working on grant-supported research projects, see "Salaries and Wages" in this subsection. See "National Research Service Awards—Individual National Research Service Awards (Fellowships)—Financial Provisions—Other Costs—Tuition and Fees" and "National Research Service Awards—Institutional National Research Service Awards (Training Grants)—Financial Provisions—Other Direct Costs—Trainee Tuition and Fees" 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."

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 a fringe benefit (see "Fringe Benefits" in this subsection). See "National Research Service Awards—Individual National Research Service Awards (Fellowships)—Other Terms and Conditions—Leave" and "National Research Service Awards—Institutional National Research Service Awards (Training Grants)—Other Terms and Conditions—Leave" for NIH policy on leave for fellows and trainees.

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 designated 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 designated GMO if it intends to engage in these activities. (Also see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying" and "Administrative Requirements—Monitoring—Reporting" concerning lobbying restrictions 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 employees or their beneficiaries) in lieu of the method described above. Under this method, the benefits may be charged in the grantee's fiscal year in which the payments are made to, or on behalf of, retired employees or their beneficiaries, provided that the grantee follows a consistent policy of treating such payments as expenses in the year of payment. See the applicable cost principles for additional information on the allowability of costs associated with pension plans.

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 the grant, if awarded, without NIH 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 direct costs but should be treated as F&A costs if they benefit more than one sponsored agreement or if they benefit the grant and other work of the organization.

Publications: Allowable. Page charges for publication in professional journals 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, also are 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, Intellectual Property Rights, and Sharing Biomedical 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 (also see "Travel" and "Relocation Costs" in this subsection.

Registration Fees (for Symposiums and Seminars): Allowable if necessary to accomplish project objectives.

Relocation Costs: Allowable—in other than change of grantee organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the grantee's benefit rather than the individual's, and 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 costs that may be charged to NIH projects generally may not exceed the amount that would be allowed if the grantee continued to own the property.

Rental costs under less-than-arms-length leases are allowable only up to the amount that would be allowed under the applicable cost principles had title to the property been vested in the grantee. A "less-than-arms-length" lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), 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 individuals, including patients and volunteers, participating in research programs are allowable. For grants that are not subject to expanded authorities (see "Administrative Requirements—Changes in Project and Budget"), NIH prior approval always is required to incur patient care costs if not previously approved by NIH, to rebudget additional funds into, or to rebudget funds out of the research patient care costs category. For grants subject to expanded authorities, NIH prior approval is required only if the incurrence of patient care costs represents a change in scope.

"Routine services" include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made. "Ancillary services" are those special services for which charges 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" for NIH policy concerning reimbursement of these costs.

The following otherwise allowable costs are not classified as research patient care costs: items of personal expense reimbursement, such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors. Such costs should be included in the "Other Expenses" category of the grant budget.

Reserve Funds: Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see "Contingency Funds" in this subsection).

Sabbatical Leave Costs: Sabbatical leave costs may be included in a fringe benefit rate or in the organization's F&A rate. Salary may be charged directly to a project for services rendered to the project by individuals while they are on sabbatical leave, provided the salary is proportional to the service rendered and is paid according to established organizational policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of that individual's regular salary from his or her organization.

Salaries and Wages: Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project. Compensation costs are allowable to the extent that they are reasonable; conform to the established policy of the organization consistently applied regardless of the source of funds; and reflect no more than the percentage of time actually devoted to the NIH-funded project. As required in its annual appropriations act, NIH will not reimburse grantees for the direct salaries of individuals at a rate in excess of the level specified in the appropriations language. Direct salary is exclusive of fringe benefits and F&A costs. This salary limitation does not apply to consultant payments or to contracts for routine goods and services but does apply to consortium participants (see "Consortium Agreements").

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 also must 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 organizational 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 under research grants (including fellows and trainees) are allowable, provided:

- The individual is performing activities necessary to the grant;
- Tuition remission and other forms of compensation are provided in accordance with established institutional policy, consistently provided to students performing similar activities conducted in non-sponsored as well as in sponsored activities; and
- During the academic period, the student is enrolled in an advanced degree program at a grantee or affiliated institution and the activities of the student in relation to the federally sponsored research project are related to the degree program.

Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages are subject to the reporting requirements in section J.8. of OMB Circular A-21, or an equivalent method for documenting the individual's effort on the research project. Tuition remission may be charged on an average rate basis. NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of OMB Circular A-21 and its current operating guidelines.

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 research training grants and fellowships. These payments are made according to a pre-established 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—Individual National Research Service Awards (Fellowships)—Financial Provisions—Stipends—Stipend Supplementation" and "National Research Service Awards—Institutional National Research Service Awards (Training Grants)—Financial Provisions—Stipends—Stipend Supplementation." Stipends are not allowable under research grants even when they appear to benefit the research project.

Subject Costs: See "Research Patient Care" in this subsection.

Supplies: Allowable.

Taxes: Allowable. Such costs include taxes that an organization is required to pay as they relate to employment, services, travel, rental, or purchasing for a project. Grantees must avail themselves of any tax exemptions for which activities supported by Federal funds may qualify. State sales and use taxes for materials and equipment are allowable only when the State does not grant a refund or exemption on such taxes.

Termination or Suspension Costs: Unallowable except as 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 NIH IC.

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—Institutional National Research Service Awards (Training Grants)—Financial Provisions—Other Direct Costs" 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, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile.

Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the U.S. and its possessions 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 those 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. The cost of travel under a ticket issued by a U.S. flag air carrier that leases space on a foreign air carrier under a code-sharing agreement is allowable if the purchase is in accordance with GSA regulations on U.S. flag air carriers and code shares (http://www.policyworks.gov/org/main/mt/homepage/mtt/ftr/newftr/301-10_134.html). (A code-sharing agreement is an arrangement between a U.S. flag carrier and a foreign air carrier in which the U.S. flag carrier provides passenger service on the foreign air carrier's regularly scheduled commercial flights.)

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

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

HUMAN SUBJECTS

INFORMATION ON OBTAINING A FEDERALWIDE ASSURANCE (FWA) (Section 6a) <u>OR</u> A SINGLE PROJECT ASSURANCE (SPA) (Section 6b) FOR GRANTS THAT INVOLVED HUMAN SUBJECTS

<u>NOTE</u>: IF A GRANTEE DOES NOT HAVE A MULTIPLE PROJECT ASSURANCE, GRANTEES MUST OBTAIN A FWA OR A SPA WHEN HUMAN SUBJECTS ARE INVOLVED IN THEIR RESEARCH UNLESS THEIR STUDY IS CONSIDERED EXEMPT

FEDERALWIDE ASSURANCE (FWA)

Section 6a

IRB Registration and Assurance Filing Procedures General Information

Why Register an IRB or IEC?

Registration will facilitate DHHS's effort to establish effective communication with IRBs and IECs working to protect human subjects, especially those responsible for HHS-regulated or HHS-supported research. Registered IRBs will benefit from emerging technologies to make communication to and from HHS quick and easy.

At the present time, Registration is required only for IRBs and IECs designated under an OHRP Federalwide Assurance of Protection for Human Subjects. However, other IRBs and IECs are encouraged to register voluntarily. IRB Registration is not currently required by FDA.

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What is an "Assurance" and When is an "Assurance" Needed?

The Federal Policy (Common Rule) for the protection of human subjects at Section 103(a) requires that each institution "engaged" in Federally-supported human subject research file an "Assurance" of protection for human subjects. The Assurance formalizes the institution's commitment to protect human subjects. The requirement to file an Assurance includes both "awardee" and collaborating "performance site" institutions.

Under the Federal Policy (Common Rule) at Section 102(f) awardees and their collaborating institutions become "engaged" in human subject research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release, or access individually identifiable private information for research purposes.

In addition, awardee institutions are automatically considered to be "engaged" in human subject research whenever they receive a direct HHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award. The awardee is also responsible for ensuring that all collaborating institutions engaged in the research hold an OHRP approved Assurance prior to their initiation of the research.

See OHRP guidance on Engagement of Institutions in Research for detailed examples of when institutions do or do not become engaged in human subjects research, and thus do or do not need an Assurance. Use the "Back" button on your browser to return to this page after reviewing the OHRP guidance.

[Return to IRB Registration & Assurance Filing Main Page]

What Happens to Existing Assurances (MPAs, CPAs, SPAs)

Existing Multiple Project Assurances (MPAs) and Cooperative Project Assurances (CPAs) will remain in effect through their current expiration date, or December 31, 2003 (whichever comes first). Single Project Assurances (SPAs) will remain in effect through the expiration of their respective grant or contract award and any non-competetive continuation. Of course, coverage under these Assurances will be limited to that described in the Assurance.

Institutional Review Boards (IRBs) designated under currently approved MPAs were Registered automatically. Any update of IRB information should be submitted to OHRP by completing the IRB Registration form [instructions at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm], checking update and providing IORG and IRB identifiers found on the web [at http://ohrp.osophs.dhhs.gov/irbasur.htm#IRB].

If they wish to be registered with HHS, IRBs currently designated only under CPAs or SPAs will have to submit registration materials through the new system.

Note that each legally separate entity that engages in federally-supported human subject research needs its own Assurance under the new system. Joint Assurances, and Interinstitutional Amendments have been eliminated. However, institutions may to designate IRBs under their Assurances that are operated by other entities.

[Return to IRB Registration & Assurance Filing Main Page]

If you have questions about human subject research, click ohrp@osophs.dhhs.gov
If you have questions/suggestions about this web page, click Webmaster
Updated March 20, 2002

U. S. Department of Health and Human Services (DHHS)
Office for Human Research Protections (OHRP)

Step-by-Step Instructions for Filing a Federalwide Assurance for International (Non-U.S.) Institutions

Version Date 03/20/2002

Each institution that is engaged (see definition of "engaged" at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm) in Department of Health and Human Services (DHHS) supported or conducted human subject research must submit a Federalwide Assurance (FWA) to the Office for Human Research Protections (OHRP). The FWA Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally-binding agreement.

Follow the instructions below for each item on the application. You should also review the Questions and Answers material found at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/afaq.htm. If you have further questions **after reading these instructions and reviewing the Questions and Answers,** please go to the staffing guide at http://ohrp.osophs.dhhs.gov/dpa-staff.htm#Table2 , to determine the name and phone number of the staff member assigned to your region and contact them.

TOP RIGHT-HAND CORNER - "New Filing" versus "Update or Renewal"

Indicate by an [x] whether this is either: 1) a "New Filing", or 2) an "Update or Renewal" of an **already existing** FWA. Your application is a "New Filing" if this is your institution's initial filing for a FWA. If your institution already has an approved FWA, the form should be appropriately marked as an "Update or Renewal" and include your institution's FWA number. (See Update and Renewal instructions at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/renwfwa.htm)

ITEM #1 - Institution Filing Assurance

a. Type or print the legal name of the institution (or the name the institution uses in doing business) that is providing the Assurance. Please **do not provide both names in this section**. Any alternate name(s) or components of the institution filing the FWA or separate legal entities that will be covered by the FWA should be listed under Item #2 of the FWA application.

   Institutions that are affiliated solely through professional or collaborative arrangements must submit their own FWA application, unless a special exception is requested and described in a cover letter submitted with the FWA application, and approved by OHRP. An exception may be made by OHRP as described in the following example.

   Separate legal entities may be covered under one FWA, if there is one human subjects protection program that oversees the review and conduct of human subjects research at each entity or institution. In such cases, the Signatory Official who signs the FWA must have authority over the entire human subjects protection program and be ultimately responsible for the review and conduct of human subjects research at each component and separate legal entity covered

under the FWA. A formal agreement between each separate legal entity should be prepared to outline the relationship between the institutions and document the authority granted to the Signatory Official with regard to the oversight of human subjects research at each institution. A copy of the agreement should be kept on file at each institution and made available to OHRP upon request.

Do not hesitate to contact OHRP if consultation is needed on this issue.

Any component that does business in its own name (e.g., applies for federal research funding in its own name and/or has its own IPF/EIN identifiers, described below in paragraph c) may file its own FWA application, if the organization's administrative structure permits the component to make legally binding commitments to the Terms of Assurance, independent of the "parent" institution. Such a decision may be appropriate if the component has its own human subjects protection program that is separate or distinct from the "parent" institution.

b. Type or print the city, country and mail code where the institution is located.

c. Type or print the DHHS Institution Profile File (IPF) code and the Federal Entity Identification Number (EIN; tax number), if known. OHRP does not assign these numbers; they are assigned by other federal departments or agencies for certain tracking purposes. OHRP requests these numbers to distinguish between similar institutions and to try to avoid approval of multiple assurances for a given institution. If your are not aware of your institution's IPF code or EIN, you may leave these items blank. The numbers are not required for FWA processing.

Indicate whether your FWA will replace a Multiple Project Assurance (MPA; "M" number) or a Cooperative Project Assurance (CPA; "T" number), by providing the respective number of your current Assurance.

ITEM #2 - Institutional Components

Type or print the names of all components of the institution identified in item #1 that will be covered by the FWA, including any alternate names used by your institution or components. Components are generally defined as parts of your institution that may be viewed as separate organizations, but remain part of the legal entity or institution.

For example, a ABC University can list its XYZ University Hospital, KLM School of Public Health, and EFG Institute for International Studies as components. In order to keep the listing of components manageable, only list the major components of your institution that are likely to be represented as either the applicant organization or as a research performance site. Please do not list all departments of your institution, as their participation in a study is likely to be represented by the name of the institution or one of the major components.

ITEM #3 - Statement of Principles

Indicate by an [x] the statement of ethical principles that govern your institution in fulfilling its responsibilities for the protection of the rights and welfare of human subjects in research. OHRP recognizes The Belmont Report as an acceptable statement of ethical principles for the protection of human subjects in research. International institutions may elect the Declaration of Helsinki as their statement of ethical principles for the protection of human subjects in research. If "Other" principles are named, as required by the human subjects protection regulations, a copy of those principles must be submitted with the FWA application.

ITEM #4 - Applicability

a. Review the Terms of the Federalwide Assurance (FWA) for International (non-U.S.) Institutions on the OHRP website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasurt.htm to obtain an understanding of the regulatory requirement that will be applied to federally-supported or -conducted human subjects research.

b. This section asks about the regulatory standards that your institution applies to human subjects research. Indicate with an [x] the alternative regulatory standards available on the FWA application for International Institutions (non-U.S.) that your institution elects to apply for U.S. federally-supported or -conducted human subjects research.

   Please note that the listed alternative regulatory standards are considered to be generally consistent to the U.S. Common Rule (i.e., U.S. Federal Policy for the protection of human subjects in research). However, for DHHS-supported or -conducted human subjects research item 7 of the Terms of the FWA for International (non-U.S.) Institutions may require additional protections for the involvement of pregnant women or fetuses, prisoners, or children.

   If "Other" procedural standards are named, a copy of those standards must be submitted with the FWA application.

ITEM #5 - Designation of Institutional Review Boards(s)/Independent Ethics Committee(s)

Designate the Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) of record for this assurance. You must still indicate at least one IRB/IEC in this section. Please ensure that all designated IRBs/IECs are registered, or are in the process of registering, with OHRP prior to submitting the FWA application. OHRP does not take action on a FWA application until all designated IRBs/IECs are registered and assigned IRB Registration numbers. If the registration of the IRB/IEC was in process when you submitted your FWA, OHRP will insert the IRB Registration number.

To determine if an IRB/IEC is registered with OHRP, you should go to the OHRP website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fiorg.htm and search for it. If an IRB(s) needs to be registered, go to the instructions on the OHRP website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm - with links to sample registrations in Rich Text and HTML Formats.

List the IRB Registration number(s) [not the IRB Organization number (IORG number)] and the name of the IRB(s) as registered on this website.

If your institution relies on another institution's IRB/IEC, this arrangement must be documented in writing between the two institutions. OHRP has a sample IRB Authorization Agreement on its website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/irbasur.htm that may be used for this purpose, or the institutions may develop their own agreement. The agreement must be kept on file at the institutions and available for review by OHRP upon request, but it should not be submitted with the FWA application.

If at any time your institution relies on an IRB/IEC not listed on your FWA, you must update your FWA and list the additional IRB(s)/IEC(s). (See Update and Renewal instructions on the OHRP website at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/renwfwa.htm)

***ITEM #6* - Human Protections Administrator** Designate the individual who will serve as the Human Protections Administrator (HPA)(i.e., the primary contact person for human subjects protection issues) for your institution. The HPA whould exercise operational responsibility for your institution's program for protecting human subjects in research. The HPA should have comprehensive knowledge of all aspects of your institution's system of protections for human subjects, as well as be familiar with the institution's commitments under the FWA and play a key role in ensuring that the institution fulfills its responsibilities under the FWA.

When considering who should be appointed as HPA, it is important to remember that the duration of an FWA is 3 years and that, at the institution's option, a FWA may cover all human subjects research at the filing institution, not just federally-supported or -conducted human subjects research. The HPA should be familiar with the institution's commitments under the FWA and that the HPA is responsible for assisting the institution in ensuring that it fulfills its responsibilities.

Type or print the full name, degree(s), institutional (e.g., administrative) title, institution, telephone and fax numbers, e-mail address, and full mailing address for the HPA. The e-mail address is very important, as this will provide the means for effective communication from OHRP (e.g., sending of new information regarding the FWA). If any of these fields are not available, please indicate accordingly rather than leaving the field blank. NOTE, you may also obtain news items and new guidance from OHRP by signing up on the OHRP-L LISTSERV (instructions are found on the OHRP website at http://ohrp.osophs.dhhs.gov/list.htm)

***ITEM #7* - Signatory Official**

The Signatory Official must be a senior institutional official who has the authority to commit the entire institution named in the FWA application, as well as all of the institutional components listed under Item #2, to a legally binding agreement. Entities that the Signatory Official is not legally authorized to represent may not be covered under the FWA. This individual must also have the authority to assure compliance of the institution and all of its components to the Terms of the Assurance. Generally, this is someone at the level of President or Chief Executive Officer (CEO) of a company or Provost or Chancellor of an academic institution, unless another official has been specifically delegated with this authority. **Thus,the IRB Chair and IRB members are not appropriate personnel to serve as the Signatory Official.**

The signature of the Signatory Official and the date of the signature must be provided on the FWA. The FWA with the original signature must be submitted to OHRP.

Type or print the full name, degree(s), institutional (e.g., administrative) title, institution, telephone and fax numbers, e-mail address, and full mailing address for the Signatory Official. The e-mail address is very important, as this will provide the means for effective communication from OHRP (e.g., sending of new information regarding the FWA). If any of these fields are not available, please indicate accordingly rather than leaving the field blank. NOTE, you may also obtain news items and new guidance from OHRP by signing up on the OHRP-L LISTSERV (instructions are found on the OHRP website at http://ohrp.osophs.dhhs.gov/list.htm)

***ITEM #8* - DHHS Approval**

Leave this item blank. This section is for use by OHRP for approval of the FWA.

***Submitting an FWA Application to OHRP* -**

Please review and proofread all materials to be submitted and ensure that all parts of the FWA application are complete and accurate. **Applications that are complete will facilitate quicker review and approval by OHRP. Incomplete documents may delay processing and approval of the FWA.**

Please submit the FWA application single-sided and with the original signature of the Signatory Official by regular mail, express mail, or hand delivery to OHRP at:

FWA Submission
Division of Assurances and Quality Improvement
Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

FWA applications may be submitted by fax to 011-301-402-0527, as long as the FWA with the original signature(s) follows by mail. (Note, IRB registrations are also acceptable via fax at the above number.)

Notification of Approval of a FWA -

Notice of approval of a FWA will be sent by e-mail to the Signatory Official and the Human Protections Administrator if e-mail addresses were provided for them on the FWA application. A copy of the approved FWA will be sent by regular mail to the Signatory Official.

[SAMPLE DOCUMENT- Rich Text Format (RTF)]

[SAMPLE DOCUMENT- HyperText Markup Language Format (HTML)]

If you have any questions, please do not hesitate to contact the Division of Assurances and Quality Improvement, OHRP, at 011-301-496-7005.

If you have questions about human subject research, click ***ohrp@osophs.dhhs.gov***
If you have questions/suggestions about this web page, click ***Webmaster***
Updated May 31, 2002

Version Date 03/20/2002

U. S. Department of Health and Human Services (DHHS)
Office for Human Research Protections (OHRP)

FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS

A. TERMS OF THE FEDERALWIDE ASSURANCE FOR INSTITUTIONS WITHIN THE UNITED STATES

1. Human Subject Research Must be Guided by Ethical Principles

All of the Institution's human subject activities and all activities of the Institutional Review Boards (IRBs) designated under the Assurance, regardless of funding source, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by Federal Departments and Agencies that have adopted the Federal Policy for the Protection of Human Subjects.

2. Applicability

These terms apply whenever the Institution becomes engaged in federally-supported* (i.e., conducted or supported) human subject research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects. The Institution becomes so engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of federally-supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of federally-supported research; or (c) the Institution receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

[*Federally-supported is defined throughout the FWA and the Terms of Assurance as the U.S. Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves U.S. Government employees.]

3. Compliance with the Federal Policy for the Protection of Human Subjects

Institutions conducting federally-supported human subject research and the IRB(s) designated under the Institution's Assurance will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule. All federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All human subject research conducted or supported by the Department of Health and Human Services (DHHS) will comply with all Subparts of DHHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D).

The reference in the Code of Federal Regulations is shown below for each Agency which has adopted the Common Rule:

7CFR 1c	Department of Agriculture
10 CFR 745	Department of Energy
14 CFR 123	National Aeronautics and Space Administration
15 CFR 27	Department of Commerce
16 CFR 1028	Consumer Product Safety Commission
22 CFR 225	Agency for International Development
24 CFR 60	Department of Housing and Urban Development
28 CFR 46	Department of Justice
32 CFR 219	Department of Defense
34 CFR 97	Department of Education
38 CFR 16	Department of Veterans Affairs
40 CFR 26	Environmental Protection Agency
45 CFR 46	Department of Health & Human Services
45 CFR 690	National Science Foundation
49 CFR 11	Department of Energy
By Executive Order	Central Intelligence Agency
By Statue	Social Security Administration

4. Written Procedures

a) The Institution should establish, and should provide a copy to OHRP upon request, written procedures for:

1) ensuring prompt reporting to the IRB, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any: (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval.

2) Verifying, by a qualified person or persons other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the Common Rule;

b) The designated IRB(s) has established, and will provide a copy to OHRP upon request, written procedures for:

1) Conducting IRB initial and continuing review (not less than once per year), approving research, and reporting IRB findings to the investigator and the Institution;

2) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review;

3) Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

5. Responsibilities and Scope of IRB(s)

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, all human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s). The IRB(s) will have authority to approve, require modifications in, or disapprove the covered human subject research.

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, informed consent will be:

a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 116 of the Common Rule;

b) appropriately documented, in accordance with, and to the extent required by Section 117 of the Common Rule.

7. Requirement for Assurances for Collaborating Institutions/Investigators

The Institution is responsible for ensuring that all institutions and investigators engaged in its U.S. federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of the supporting Department or Agency and the institution holding the Assurance.

8. Written Agreements with Non-Affiliated Investigators

The engagement in human research activities of each independent investigators who is not an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the Institution may develop its own commitment agreement. Institutions must maintain commitment agreements on file and provide copies to OHRP upon request.

9. Institutional Support for the IRB(s)

The Institution will provide the IRB(s) that it operates with resources and professional and support staff sufficient to carry out their responsibilities under the Assurance effectively.

10. Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-9 above and is responsible for ensuring that (a) the IRB(s) designated under the Assurance agree to comply with these terms; and (b) the IRB(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance (please refer to the OHRP guidance on IRB Knowledge of Local Research Context on the

OHRP website).

Any designation under this Assurance of another Institution's IRB or an independent IRB must be documented by a written agreement between the Institution and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. OHRP's sample IRB Authorization Agreement may be used for such purpose or the two organizations may develop their own agreement. This agreement should be kept on file at both organizations and made available to OHRP upon request.

11. Assurance Training

The OHRP Assurance Training Modules describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator, and the IRB Chair(s) that must be fulfilled under the Assurance. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these modules, prior to submitting the Assurance.

12. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.

13. Renewal of Assurance

All information provided under this Assurance must be updated at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the Institution's FWA for the protection of human subjects.

DOMESTIC INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS

[Return to IRB Registration & Assurance Filing Main Page]

B. TERMS OF THE FEDERALWIDE ASSURANCE (FWA) FOR INTERNATIONAL (NON-U.S.) INSTITUTIONS

1. Human Subject Research Must Be Guided by Ethical Principles

All of the Institution's human subject activities and all activities of the Institutional Review Boards

(IRBs) or independent ethics committees (IECs) designated under the Assurance, regardless of funding source, will be guided by one of the following statements of ethical principles: (a) The World Medical Association's Declaration of Helsinki (as adopted in 1996 or 2000); (b) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or (c) other appropriate international ethical standards recognized by Federal Departments and Agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects.

2. Applicability

These terms apply whenever the Institution becomes engaged in U.S. federally-supported* (i.e., conducted or supported) human subject research, which is not otherwise exempt from the U.S. Federal Policy for the Protection of Human Subjects. The Institution becomes engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of U.S. federally-supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of U.S. federally-supported research; or (c) the Institution receives a direct award to conduct U.S. federally-supported human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.
If a U.S. Department or Agency Head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided by the U.S. Federal Policy, the Department or Agency Head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided above consistent with the requirements of 101(h) of the U.S. Federal Policy.

[*Federally-supported is defined throughout the Assurance document and the Terms of Assurance as the U.S. Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves U.S. Government employees.]

3. Compliance with Regulations, Policies, or Guidelines

All U.S. federally-supported human subject research will comply with the requirements of any applicable U.S. Federal regulatory agency as well as one or more of the following:

a) The U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule (e.g., Subpart A)or the U.S. Department of Health and Human Services (DHHS) regulations at 45 CFR 46 and its Subparts A, B, C, and D;

b) The May 1, 1996, International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6), Sections 1 through 4;

c) The 1993 Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects;

d) The 1998 Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans;

e) The 2000 Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects; or

f) Other standard(s) for the protection of human subjects recognized by U.S. Federal Departments

and Agencies which have adopted the U.S. Federal Policy for the Protection of Human Subjects.

4. IRB/IEC Written Procedures

a) The Institution should establish, and should provide a copy to OHRP upon request, written procedures for:

1) ensuring prompt reporting to the IRB/IEC, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any: (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval.

2) Verifying, by a qualified person or persons other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the U.S. Common Rule;

b) The designated IRB(s)/IEC(s) should establish, and should provide a copy to OHRP upon request, written procedures for:

1) Conducting IRB/IEC initial and continuing review (not less than once per year), approving research, and reporting IRB/IEC findings to the investigator and the Institution;

2) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB/IEC review;

3) Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB/IEC review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

5. Responsibilities and Scope of IRB(s)/IEC(s)

Except for research exempted or waived in accordance with sections 101(b) or 101(i) of the U.S. Common Rule, U.S. federally-supported research should be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s)/IEC(s). The IRB(s)/IEC(s) should have authority to approve, require modifications in, or disapprove the covered human subject research.

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the U.S. Common Rule, informed consent should be:

a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 116 of the U.S. Common Rule;

b) appropriately documented, in accordance with, and to the extent required by Section 117 of the U.S. Common Rule.

7. Considerations for Special Class of Subjects

For DHHS-supported human subject research, this Institution will comply with 45 CFR 46 Subparts B, C, and D prior to the involvement of pregnant women or fetuses, prisoners, or children, respectively. For non-DHHS U.S. federally-supported human subject research, the Institution will comply with any human subject regulations and/or policies of the supporting Department or Agency for these classes of subjects.

8. Requirement for Assurances for Collaborating Institutions/Investigators

The Institution is responsible for ensuring that all institutions and investigators engaged in its U.S. federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of the supporting Department or Agency and the institution holding the Assurance.

9. Written Agreements with Non-Affiliated Investigators

The engagement in human research activities of each independent investigator who is not an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the Institution may develop its own commitment agreement. Institutions must maintain commitment agreements on file and provide copies to OHRP upon request.

10. Institutional Support for the IRB(s)/IEC(s)

The Institution should provide the IRB(s)/IEC(s) that it operates with resources and professional and support staff sufficient to carry out their responsibilities under the Assurance effectively.

11. IRB(s)/IEC(s) Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-10 above and is responsible for ensuring that (a) the IRB(s)/IEC(s) designated under the Assurance agree to comply with these terms, and (b) the IRB(s)/IEC(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance (please refer to the OHRP posted guidance on IRB Knowledge of Local Research Context).

Any designation under this Assurance of another Institution's IRB or an independent IRB must be documented by a written agreement between the Institution and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. OHRP's sample IRB Authorization Agreement may be used for such purpose or the two organizations may develop their own agreement. This agreement should be kept on file at both organizations and made available to OHRP upon request.

12. Assurance Training

The OHRP Assurance Training Modules describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator and the IRB Chair(s) that must be fulfilled under the Assurance. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB/IEC Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these Modules, prior to submitting the

Assurance.

13. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s)/IEC(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB/IEC members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant U.S. regulations; procedural standards under the Assurance; OHRP guidance; other applicable guidance; national, state and local laws; and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB/IEC members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.

14. Renewal of Assurance

All information provided under this Assurance should be updated every 36 months (3 years), even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the Institution's Federalwide Assurance for the protection of human subjects.

INTERNATIONAL INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS

[Return to IRB Registration & Assurance Filing Main Page]

If you have questions about human subject research, click ***ohrp@osophs.dhhs.gov***
If you have questions/suggestions about this web page, click ***Webmaster***
Updated March 20, 2002

Office for Human Research Protections (OHRP)

IRB Registration and Federalwide Assurance (FWA) Questions and Answers

1. **How does an IRB register with HHS?**

   All IRBs are eligible to register with HHS/OHRP. Simply (i) go to OHRP's IRB Registration and Assurance website (http://ohrp.osophs.dhhs.gov/irbasur.htm); (ii) download, complete, and forward to OHRP the 3-page IRB registration form (http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm); and (iii) in 3-5 days, check OHRP's IRB registration listings to verify that processing has been completed (http://ohrp.osophs.dhhs.gov/polasur.htm#LST).

2. **How does an institution file a Federalwide Assurance (FWA) with HHS?**

   Any institution is eligible to file an FWA with HHS/OHRP. Simply: (i) check OHRP's IRB registration listings (http://ohrp.osophs.dhhs.gov/humansubjects/assurance/iorg-a-f.htm) for IRB(s) to be designated under the FWA; (ii) if listed, proceed to (iii) -- if not listed, the IRB(s) should file the 3-page IRB registration form (http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm); (iii) download, complete, and forward to OHRP the 4-page FWA form (http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasuri.htm); (iv) In FWA Item 5, supply in the Registration Number and Name of the IRB and have the designation signed by an IRB Official; (v) in 5-7 days, check the FWA listings (http://ohrp.osophs.dhhs.gov/humansubjects/assurance/cfed-a-c.htm) to verify approval; (vi) once approved, human subjects research can begin. OHRP will return a copy of the signed FWA for institutional records.

3. **Under what circumstances can one institution rely on another organization's IRB?**

   Institution A can rely on Organization B's IRB any time Organization B's registered IRB agrees to the arrangement and satisfies the guidelines for knowledge of the local research context (see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/local.htm). If such reliance reflects an on-going arrangement, Organization B's IRB should be designated in Item 5 of Institution A's FWA. The Head of Organization B or the IRB Chairperson must sign the designation in FWA Item 5. If the reliance is an unexpected, one-time arrangement, institutions with FWAs can use the sample "IRB Authorization Agreement for an Individual Protocol" on OHRP's website.

4. **Under the old system, institutions could file Joint Assurances, Cooperative Amendments, and InterInstitutional Amendments (IIAs) to cover cooperative IRB review arrangements. How are such arrangements handled with FWA's?**

   Each legally separate entity needs its own FWA. However, any registered IRB can be designated under an institution's FWA, as long as the IRB Organization agrees to the designation and satisfies

the guidelines for knowledge of the local research context. FWA Item 5 should list all IRBs that the institution may rely upon under any cooperative IRB review arrangement. No additional documentation need be provided to OHRP. Of course, written policies and procedures should define the human protection responsibilities of all involved parties.

5. How are "unaffiliated" investigators and physicians in private practice settings covered under the new system?

Investigators who are not acting as employees or agents of an FWA institution (or MPA or CPA institution where applicable) when they conduct Federally-supported human subject research are nevertheless subject to all of the usual human protection requirements. Such investigators must enter into an arrangement with an FWA institution (or MPA or CPA institution where applicable) under which they agree to be bound by the human protection policies of the institution and its designated IRB(s). The "Unaffiliated Investigator Agreement" on OHRP's website may be used for this purpose. The agreement should not be forwarded to OHRP. Individual physicians operating in private practice settings that are not covered under an Assurance may follow the same procedure. Alternatively, a group of physicians operating within their own private practice may choose to file an FWA in the name of their practice.

6. What are the Education requirements for Domestic Institutions under the FWA?

The Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chairperson(s) must complete the OHRP basic educational modules (or training certified to OHRP by the institution as equivalent to the OHRP modules) prior to submitting the Assurance. Members and staff of the IRBs must complete relevant training before reviewing human subject research. Research investigators must complete appropriate institutional training before conducting human subject research. (i) OHRP will check to verify that the Signatory Official and the Human Protections Administrator have completed the OHRP Assurance Training Module before approving the FWA -- unless the institution certifies to OHRP that these individuals have taken equivalent training. These individuals should indicate their role upon entering the module. (ii) OHRP will check to verify that the IRB Chairperson has completed the OHRP module when an institution designates an IRB under an FWA. IRB Chairs should indicate their role upon entering the module. (iii) OHRP expects that IRB members and IRB staffs will be appropriately trained. Although they may complete the OHRP module (identifying their role as "other"), OHRP expects that many institutions will decide that other types of training are more appropriate for these individuals. OHRP will expect institutions to be able to provide details about their training upon request. (iv) Individuals who are not Signatory Officials, Human Protections Administrators, and IRB Chairs may take the OHRP module training. They should identify their role as "other" and OHRP will not track their completion of the module. However, we hope soon to offer a downloadable certificate to acknowledge their training.

7. What are the Education requirements for International Institutions under the FWA?

The Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), the IRB Chairperson(s), IRB members, IRB staff, and research investigators must be appropriately trained in the protection of human subjects. Upon request, they should be able to demonstrate knowledge of the FWA Terms of Assurance for Institutions Outside the United States, and of the Ethical Standards and International Codes referenced in their institution's FWA.

8. Who may serve as the Signatory Official on an FWA?

The FWA Signatory must be a high institutional official who has the legal authority to represent the institution named in the FWA, as well as all the institutional components listed in the FWA. Entities that the Signatory Official is not legally authorized to represent

may not be covered under the FWA.

9. Who/What is the Human Protections Administrator?

The Human Protections Administrator is an employee or agent of the FWA institution who exercises operational responsibility, on a day-to-day basis, for the institution's program for protecting human subjects. This individual's title and position within the institutional structure will vary from institution to institution. What is important is the individual's comprehensive knowledge of all aspects of the institution's systemic protections for human subjects. Every domestic FWA institution should have a Human Protections Administrator, even if the institution relies totally on IRBs from other organizations (see below).

10. If an institution has no IRB and designates another organization's IRB(s) in its FWA, what are the institution's responsibilities for protecting human subjects?

When institutions rely upon another organization's IRB, they remain responsible for maintaining an institutional system to protect human subjects (see item (C) of OHRP guidance at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/local.htm). They can choose to have some of those responsibilities handled by the IRB organization if they so desire, but the respective responsibilities of the IRB organization and the Assuring institution should be put in writing (although this agreement does not need to be sent to OHRP for approval). The institution providing the FWA retains ultimate responsibility for the protection of human subjects in all research in which the institution engages, including (i) safeguarding the rights and welfare of human subjects within its local research context; (ii) educating the members of its research community in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human subjects; and (iii) implementing, within its local research context, appropriate oversight mechanisms to ensure compliance with the determinations of the reviewing IRB.

11. If an institution relies upon the IRB of another organization, how should it answer the questions at FWA Item 4?

These items refer to the Assuring institution's overall human subject protection program, and should be answered from that perspective. As long as there are clear written policies defining areas of responsibility (see above), it does not matter whether the responsibilities in Items 4(a), 4(b), and 4(c) are actually implemented by the Assuring institution or by the IRB organization acting on behalf of the Assuring institution. Item 4(d) refers to the Signatory Official, the Human Protections Administrator, and relevant staff at the Assuring institution, as well as to the Chairpersons of all IRBs designated under the FWA. Item 4(e) refers to personnel at the Assuring institution only.

12. Will OHRP continue to accept MPAs. CPAs, and SPAs?

During the initial implementation phase (i.e., approximately through February 2001), OHRP will continue to accept CPAs and SPAs whose negotiation has already been initiated. As the implementation proceeds, OHRP will announce a final date after which CPAs and SPAs will no longer be processed.

13. Existing MPAs and CPAs will remain in effect until their expiration date, or December 31, 2003, whichever comes first. What about changes in MPAs and CPAs that are needed prior to this date?

Institutions holding current MPAs and CPAs are encouraged to file an FWA at their earliest convenience. OHRP will no longer process MPA or CPA amendments or modifications, including Cooperative Amendments (CAs) and Inter-Institutional Amendments (IIAs). Institutions requiring such modifications should file an FWA.

14. What about updates to IRB membership rosters?

All institutions should use the new IRB Registration format to update their IRB membership rosters, regardless of the type of their Assurance (FWA, MPA, CPA).

15. FWA Item (1) asks for IPR and EIN numbers. What are IPF and EIN numbers? Are they required to file an Assurance?

IPF and EIN numbers are assigned by Agencies other than OHRP. Some funding Agencies use these numbers for tracking purposes. OHRP has requested them simply to assist those Agencies. If your institution has no IPF or EIN number, just leave the item blank. It is not necessary for an FWA and will not delay processing of your FWA.

[Return to IRB Registration & Assurance Filing Main Page]

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Updated June 19, 2001

SINGLE PROJECT ASSURANCE (SPA)

Section 6b

To Download in RTF Format
(for best editing results)
CLICK HERE

IMPORTANT: CONSULT OPRR BEFORE SUBMISSION. OPRR CANNOT ACCEPT UNSOLICITED ASSURANCES.

THIS IS A SAMPLE SINGLE PROJECT ASSURANCE (SPA) FOR AN INSTITUTION WHICH CURRENTLY DOES NOT HAVE A MULTIPLE PROJECT ASSURANCE (MPA) ON FILE WITH OPRR.

FULL IRB REVIEW REQUIRED OF IRB

Using this Sample, type on Institutional Letterhead, supplying where indicated, information specific to the proposed research activity and your Institution, and include required certification on the endorsement page.

click here to view common errors in SPA preparation

(Name of Institution)

Assurance of Compliance with DHHS regulations for
Protection of Human Research Subjects

(Name of Institution)_____, hereinafter known as the "institution", hereby gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects 45 CFR 46) as specified below.

PART 1

Ethical Principles and Institutional Policies Governing Research Involving Human Subjects

I. Applicability

Except for research exempted or waived under the DHHS regulations 45 CFR 46.101, Part 1 of this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to federal regulation, if:

a. the research is sponsored by this institution, or
b. the research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or

c. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
d. the research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects.

II. Ethical Principles Governing Human Subjects Research

This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and as specified below.

A. This institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice as stated in the Belmont Report and will apply these principles in all research covered by this Assurance.

B. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

III. Policies

A. This institution acknowledges that it and it's investigators bear full responsibility for the performance of all research covered by this Assurance, including full responsibility for complying with Federal, state and local laws as they may relate to such research.

B. This institution assures that before human subjects are involved in research, proper consideration will be given to:

(1) the risks to the subjects,
(2) the anticipated benefits to the subjects and others,
(3) the importance of the knowledge that may reasonably be expected to result,
(4) the informed consent process to be employed,
(5) the provisions to protect the privacy of subjects, and
(6) the additional safeguards for vulnerable populations.

C. This institution recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

D. This institution encourages and promotes constructive communication among the institutional officials, research administrators, department heads, research investigators, clinical care staff, human subjects, and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

E. This institution will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

Part 2

IRB, Institution, and Investigator Compliance with 45 CFR 46

I. Applicability

Part 2 of this Assurance applies to the following research project which is conducted or sponsored by this institution and supported by the Department of Health and Human Services (DHHS).
Project Title _____
DHHS Project Number _____
Project Principal Investigator _____

II. Institutional Responsibilities

A. This institution has complied and will continue to comply with the requirements of 45 CFR 46 as specified below.

B. In accordance with the compositional and quorum requirements of 45 CFR 46.107 and 46.108, the Institutional Review Board (IRB) designated in Part 3 and in the attached roster is responsible for the initial and continuing review of this project.

C. This institution has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties.

D. In addition to the review and approval of the IRB, this institution has reviewed and sponsors the project referenced above.

III. IRB Review

A. The IRB shall review, and have the authority to approve, require modification in, or disapprove this research activity or proposed changes in it before human subjects may be involved.

B. The convened IRB reviewed and approved the above project.

C. The IRB determined, in accordance with the criteria found at 45 CFR 46.111, and where applicable, 45 CFR 46 Subparts B, C, and D, that protections for human subjects are adequate.

D. The IRB has the authority to suspend or terminate approval of the above referenced research in accordance with 45 CFR 46.113 for (1) non-compliance with 45 CFR 46, and this Assurance document or the IRB's requirements, and (2) for elimination of unexpected serious harm to subjects.

E. The IRB has determined that legally effective informed consent **[copy of document must be attached unless specified otherwise by OPRR]** will be obtained in a manner and method which meets the requirements of 45 CFR 46.116 and 46.117.

F. Certification of IRB approval, at least annually shall be submitted to the DHHS awards unit that issued the award, as a condition for receipt of funds for a non-competing continuation and/or additional involvement of human subjects.

G. Continuing reviews by the IRB shall be conducted at intervals appropriate to the degree of risk, but not less that once per year. 45 CFR 46.109 [e]). The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or Institutional Official to consider any matter concerned with the rights and welfare of any subject.

H. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 45 CFR 46.115.

I. The IRB shall report promptly to institutional officials and the Office for Protection from Research Risks (OPRR):

(1) any serious or continuing noncompliance by investigators with the requirements of the IRB,
(2) any suspension or termination of IRB approval, and
(3) any unanticipated injuries or problems involving risks to subjects or others.

J. Where appropriate, the IRB will determine that adequate additional protections are ensured to fetuses, pregnant women, prisoners, and children as required under Subparts B, C, and D of 45 CFR 46. The IRB will notify OPRR promptly when IRB membership is modified to satisfy the requirements at 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305 (c).

K. The IRB will comply fully with the requirements of all applicable Federal policies and guidelines, including those concerning notification of sero-positivity, counseling, and confidentiality of subjects.

IV. Research Investigator Reporting Responsibilities

A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance and 45 CFR 46.

B. Research investigators shall reports promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.

C. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others.

Part 3

Certification of IRB Approval and Institutional Endorsement

Project Title

_____

DHHS Project Number

_____

Project Principal Investigator

_____

Date of IRB Approval _____(if any)

Date of Next Scheduled IRB Review _____

The officials signing below assure that the project referenced above was approved by the IRB on the date indicated and that the project will be conducted in accordance with the requirements of Part 46, Title 45 of the Code of Federal Regulations and this Assurance document. A dated roster listing the current membership of the designated IRB is attached.

As appropriate, the officials signing below further assure that for each protocol in this project for which IRB approval was not possible due to delayed onset of subject involvement, the IRB's institution will provide a copy of the IRB-approved protocol, IRB-approved consent language, and documentation of IRB certification (Optional Form 310), including the applicable Assurance number, to OPRR for approval prior to accrual of human subjects.

I. Authorized Official of the Institution Providing this Assurance

Signature _____ Date: _____

Please type the following items.

Name and Title:
Institution:
Address:

Telephone: Fax: E-mail:

II. Authorized Official of the Institution with the IRB (Include only if different from the institution above)

This institution authorizes the designation of its IRB for review of the project referenced in this Assurance.

Signature: _____ Date: _____

Please type the following items.

Name and Title:
Institution:
Address:

Telephone: Fax: E-mail:

III. IRB Chairperson (Must be completed in all cases [see IRB membership list])

Signature: _____ Date: _____

Please type the following items.

Name and Title:
Institution:
Address:

Telephone: Fax: E-mail:

MPA Number if applicable: _____

IV. Responsible Project Investigator at Institution Providing this Assurance

I have attached copies of all OPRR requested and IRB approved Informed Consent Documents tc be used in this project unless the designated IRB operates under an OPRR-approved Multiple Project Assurance (MPA) or unless OPRR has indicated otherwise.

Signature: _____ Date: _____

Please type the following items.

Name:
Title:
Institution:
Address:

Telephone: Fax: E-mail:

****

- Space Below for DHHS -

All parts of this Assurance are in compliance with the requirements of Part 46, Title 45, of the Code of Federal Regulations.

DHHS Approving Official

Signature: _____ Date: _____

Name:
Address: Assurance Coordinator, Assurance Branch
Division of Human Subject Protections
Office for Protection From Research Risks (OPRR), OD
National Institutes of Health
6100 Executive Boulevard, Suite 3B01 (MSC 7507)
Rockville, Maryland 20892-7507
Rockville, Maryland 20852 (Courier Only)

Telephone #: 301-496-7005
Fax #: 301-402-0527
E-mail address:

ASSURANCE NUMBER S- _____

An application for new or competing support for continuation in which human subjects will be involved will require a new and separate Assurance, unless the activity is exempt under section 45 CFR 46.101 (b).

For the Institutional Review Board (IRB) Membership Roster see: Institutional Review Board Members

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Pitfalls to Avoid in Preparing Your Single Project Assurance
Office for Protection from Research Risks

The following are the most common problems that result in OPRR-requested revisions to SPA documents and a delay in approval:

1. The first page of the SPA is not on institutional letterhead.

2. The "Date of IRB Approval" (see beginning of Part 3) is a date more than 12 months prior to submission of the SPA.

3. The individual signing as the "Authorized Official of the Institution Providing This Assurance" (item I, Part 3) is not the CEO, President, Director, or equivalent for the institution. The Chairman of a Department within the institution should not be signing as the Authorized Official.

4. The individual signing as the "Authorized Official of the Institution with the IRB" (item II, Part 3) is not the CEO, President, Director, or equivalent for the institution. The Chairman of a Department within the institution should not be signing as the Authorized Official.

5. The IRB Chairperson (item III, Part 3) is also the Authorized Official in items I or II. The Authorized Official of the Institution should not be the IRB Chairperson because of potential conflicts of interest.

6. The Date of the IRB Chairperson's signature precedes the "Date of IRB Approval" noted in Part 3. The IRB Chairperson should only sign the SPA **on or after the date of IRB approval.**

7. Original signatures are not provided on the SPA document.

8. Failure to consult with OPRR prior to using another institution's IRB.

9. The IRB membership roster fails to include each of the following: at least one member whose primary interests are **scientific**; at least one member whose primary interests are **non-scientific**; and at least one member who is **not affiliated** with the institution with the IRB.

10. The IRB roster includes a member who is also involved in the research project being reviewed, and the roster fails to indicate that this person was absent from the IRB meeting during the deliberations and vote on the project (such an individual may only be invited by the IRB to be present to answer questions about the project; otherwise, that person should be excluded from the meeting).

11. The consent form does not contain all of the elements of consent required by 45 CFR 46.116. Common problems include: failure to completely describe all procedures that subjects will be asked to undergo as part of the research; failure to clearly state alternative procedures or courses of treatment, if any, that may be advantageous to the subject; and failure to include the name of a contact person for questions about **"research subjects' rights"** and name of whom to contact in the event of **"research-related injury"** (contacts for these issues should include someone who is **not** a member of the research team; a member of the IRB is good contact to include in the consent form).

revised 2/5/98

Policy and Assurances | OHRP Home Page

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Updated June 23, 2000

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

Section 7

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

Release Date: June 5, 2000 (Revised August 25, 2000)

NOTICE: OD-00-039

National Institutes of Health

Policy: Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects.

Background

To bolster the Federal commitment to the protection of human research participants, several new initiatives to strengthen government oversight of medical research were announced by HHS Secretary Shalala on May 30, 2000. This announcement also reminds institutions of their responsibility to oversee their clinical investigators and institutional review boards (IRBs). One of the new initiatives addresses education and training. This NIH announcement is developed in response to the Secretary's directive.

Implementation

Before funds are awarded for competing applications or contract proposals involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research. Key personnel include all individuals responsible for the design and conduct of the study. The description of education will be submitted in a cover letter that accompanies the description of Other Support, IRB approval, and other information in accordance with Just-in-Time procedures. The use of a cover letter is also acceptable for contract proposals. After October 1, 2000, investigators submitting non-competing renewal applications for grants or annual reports for research and development contracts that involves human subjects research must also include a description of such education in their annual progress reports. This NIH policy will eventually be superceded by the DHHS Office of Research Integrity's institutional assurance on the responsible conduct of research, which is described below.

Related Training Requirement

The Office of Research Integrity (ORI), Department of Health and Human Services, is developing a policy to implement an extension of the training requirement on the responsible conduct of research (RCR) to all persons supported by PHS research. The protection of human subjects in research will be included in the RCR institutional assurance. A draft of this policy will be posted for comment on the ORI website in June, 2000.

Educational Resources

While all investigators need education in the basics of human subjects research, some may elect more intensive study if their work involves especially difficult topics or special populations. Many institutions already have developed educational programs on the protection of research participants and have made participation in such programs a requirement for their investigators. The NIH does not plan to issue a list of "endorsed" programs. Rather, the NIH points out that a number of curricula are readily available to investigators and institutions. For example, all NIH intramural investigators and research administrators who oversee clinical projects are required to complete an on-line

tutorial on the protection of human research subjects. This training can be accessed on the web site of the NIH Office of Human Subjects Research at http://ohsr.od.nih.gov/. While this training module was developed for NIH staff, it can be used by other institutions seeking to meet training requirements in this area.

To facilitate education and the development of curricula, the NIH launched a website on bioethics in 1999. (See http://www.nih.gov/sigs/bioethics/)This site is replete with resources (>4500 references) on a broad range of relevant topics, including human subjects in research, medical and healthcare ethics, and the implications of genetics and biotechnology. This website also contains a broad set of annotated web links, including some attached to training programs. In addition, the University of Rochester has made available its training program for individual investigators. Their manual can be obtained through CenterWatch, Inc. (http://www.centerwatch.com)

To address longer-term needs, the NIH has two program announcements to support training on ethical issues related to research and human subjects. The first announcement provides support (T15) for institutions to conduct short-term courses in research ethics. (See http://grants.nih.gov/grants/guide/pa-files/PA-99-051.html) The primary objectives of the T15 program are to increase knowledge among investigators regarding research ethics and to protect human participants in clinical protocols. The second announcement supports career development of individuals who are committed to a career in research ethics. These individuals will be able to serve as resources in the institutions and as catalysts in discussions of critical ethical issues in research. (See http://grants.nih.gov/grants/guide/pa-files/PA-99-050.html)

See Frequently Asked Questions for the Requirement for Education on the Protection of Human Subjects.

Also see the September 14, 2000 OER News Flash with clarification on this announcement as well as the June 29, 2001 OER News Flash and the September 5, 2001 NIH Guide Notice for additional information.

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CHANGE IN SCOPE

Section 8

Changes in Scope on NIH Grants and Coopertive Agreements

What is a change in scope?

In general, the PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the grantee must obtain prior approval from 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. The grantee must make the initial determination of the significance of a change and should consult with the GMO as necessary. **Please read the Notice of Grant Award to determine if any restrictions or conditions have been placed on the award.**

However, as noted, certain actions in the following list always require NIH prior approval under the circumstances specified. 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.
- A clinical hold by FDA under a study involving an IND or an IDE
- Applying a new technology, e.g., 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. If the third party is a foreign component, this prior approval requirement also applies to grants subject to expanded authorities.
- Change in key personnel.
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded.
- 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.
- The addition of a foreign component requires prior approval from the NIH IC'sGrants Office.

What should a grantee do if there is a change in scope?

To request approval to make a change in scope, the PI should:

1. Prepare a letter, countersigned by his/her institutional business office, that provides the reason and rationale for the change and address any budgetary impact to the grant or cooperative agreement..
2. The letter should also include revised budget pages and CVs as appropriate. Please FAX the letter to the appropriate Grants and Program staff at FIC or the other appropriate NIH Institute or Center staff.

For more information concerning changes in scope or other prior approval questions please click here to refer to the NIH Policy Statement.

We welcome your questions and comments about FIC and its research programs. Please send e-mail inquiries to the **Office of Communications.** Telephone: 301-496-2075 Fax: 301-594-1211.

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TABLE 11-2A - SUMMARY OF ACTIONS REQUIRING NIH PRIOR APPROVAL

(The information is for guidance purposes only)

ADMINISTRATIVE REQUIREMENTS

Changes in Project and Budget

In general, NIH grantees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of 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 grantee-initiated changes that may be made under the grantee's authority and the changes that require NIH approval are outlined below and in Subpart B with respect to particular types of awards, activities, or recipients. In addition, individual awards may restrict grantees' authorities to make budget and project changes without NIH prior approval. If NIH approval is required, it must be requested of, and obtained from, the designated NIH GMO in advance of the change or obligation of funds as specified below under "Requests for Approval."

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

Prior Approval Requirements

The following table (Table II-2) applies to NIH research grants and cooperative agreements to domestic organizations. See Part B for prior approval requirements that apply to other types of awards and recipients. The table lists the activities and/or expenditures that require GMO prior approval in accordance with the general terms and conditions of award (i.e., expanded authorities, Federal Demonstration Partnership (FDP), or the terms and conditions of this policy statement) and also includes activities and/or expenditures where NIH has waived the prior approval requirement on a class basis. The information in this table is for guidance purposes only. Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to the designated GMO.

* This Page Revised 3/20/2001

TABLE II-2
SUMMARY OF ACTIONS REQUIRING NIH PRIOR APPROVAL

Activity or Expenditure Requiring NIH Prior Approval	Expanded Authorities[16] (effective 12/94)	Federal Demonstration Partnership (FDP) [17] (effective 7/00)	NIH Grants Policy Statement (NIHGPS) (effective 3/01)
Change in scope	YES	YES	YES
Preaward costs (more than 90 days prior to effective date of a new or competing continuation award)	YES	YES	YES
Preaward costs for non-competing awards	At grantee's own risk	At grantee's own risk	At grantee's own risk
Change in key personnel	YES	YES	YES
Change of grantee organization	YES	YES	YES
Change in grantee organizational status	YES	YES	YES
Addition of a foreign component under a grant to a domestic organization	YES	YES	YES
Changes to award terms and conditions or undertaking any activities disapproved or restricted as a term of award	YES	YES	YES
Carryover of unobligated balances from one budget period to the next	NO	NO	YES
Extension of final budget period of a project period	NO: one extension up to 12 months allowed with no additional funds. Must notify IC no later than 10 days prior to expiration.	NO: one extension up to 12 months allowed with no additional funds. Must notify IC no later than 10 days prior to expiration.	YES

[16] The following mechanisms are routinely included in EA/FDP: P01s, Ks, and all Rs except R43 and R41.

[17] The following mechanisms are routinely included in EA/FDP: P01s, Ks, and all Rs except R43 and R41.

* This Page Revised 3/20/2001

Activity or Expenditure Requiring NIH Prior Approval	Expanded Authorities[16] (effective 12/94)	Federal Demonstration Partnership (FDP)[17] (effective 7/00)	NIH Grants Policy Statement (NIHGPS) (effective 3/01)
Equipment purchases exceeding $25,000/unit, regardless of amount of NIH funds involved	NO, unless change in scope	NO, unless change in scope	YES
Retention of research grant funds when career (K) award made	YES	YES	YES
Alteration and renovation (A&R) (rebudgeting into A&R costs exceeding 25 percent of total approved budget for a budget period)	NO, up to (and including) $300,000 YES, if>$300,000	NO, up to (and including) $300,000 YES, if>$300,000	NO, up to (and including) $300,000 YES, if>$300,000
Transferring amounts from trainee costs	YES	YES	YES
Capital expenditures (construction, land or building acquisition)	YES	YES	YES
Need for additional NIH funding	YES	YES	YES
Closely related work	YES	YES	YES
Transfer of funds between construction and non-construction work	YES	YES	YES
Program income (use of any alternative other than that specified by NIH)	NO	NO	YES
Transferring performance of substantive programmatic work to a third party (by consortium agreement, contract, or other means)	NO, unless change in scope or the third party is a foreign organization or component	NO, unless change in scope or the third party is a foreign organization or component	YES
Incurrence of patient care costs (if not previously approved or rebudgeting additional funds into or rebudgeting funds out of this category)	NO, unless change in scope	NO, unless change in scope	YES

NIH POLICY FOR FOREIGN TRAVEL ON NIH GRANTS

Section 10

NIH Policy for Foreign Travel on NIH Grants

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.

What is U.S. flag air carrier service?

U.S. flag air carrier service is service provided on an air carrier which holds a certificate under 49 U.S.C. 41102 and which service is authorized either by the carrier's certificate or by exemption or regulation. U.S. flag air carrier service also includes service provided under a code share agreement with a foreign air carrier in accordance with Title 14, Code of Federal Regulations when the ticket, or documentation for an electronic ticket, identifies the U.S. flag air carrier's designator code and flight number.

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.

In all cases, travel costs are limited to those allowed by formal organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. 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.

For more information on NIH policy concerning travel please go the NIH Grants Policy Statement by clicking here and going to the topic "Travel."

CONSORTIUM AGREEMENT INFORMATION FOR NIH GRANTS

Section 11

Consortium Agreement Information for NIH Grants

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. **In general, the requirements that apply to the grantee also apply to the consortium participant(s).**

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

At a minimum the agreement should 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;
- Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances;
- A provision addressing ownership and disposition of data produced under the consortium agreement;
- A provision making the inventions and patent policy 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;
- As appropriate, provisions regarding property (other than intellectual property), program income, publications, reporting, and audit necessary for the grantee to fulfill its obligations to NIH.
- 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.
- It is the grantee organization's responsibility to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved assurance and IRB approval of the research consistent with 45 CFR Part 46, and to comply with

NIH prior approval requirements related to the addition of sites not included in the approved application.

- The grantee is responsible for obtaining NIH approval for any actions to be undertaken by consortium participants that require such prior approval.

For more information concerning Consortiums please go refer to the NIH Policy Statement click here and look under the title "Consortium Agreements."

We welcome your questions and comments about FIC and its research programs. Please send e-mail inquiries to the **Office of Communications.** Telephone: 301-496-2075 Fax: 301-594-1211.

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REPORTING AND RECORD RETENTION GUIDANCE FOR NIH GRANTEES

Section 12

Reporting and Record Retention Guidance for NIH Grantees

Foreign grantees must submit annual Financial Status Reports (FSRs) on Standard Form SF-269, in U.S. dollars, whether or not they are under SNAP. This is due to the fact that foreign grantees are not paid through PMS and, therefore, do not submit the SF-272 (which NIH uses in lieu of the annual FSR for domestic awards under SNAP). The currency rate in 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.

Grantees generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FSR is submitted. For awards under SNAP (other than those to foreign organizations and Federal institutions), the 3-year retention period will be calculated from the date the FSR for the entire competitive segment is submitted. Those grantees must retain the records pertinent to the entire competitive segment for 3 years from the date the FSR is submitted to NIH. **Foreign organizations and Federal institutions are required to submit annual FSRs for all awards, including those under SNAP, and must retain these records for a period of 3 years from the date of submission of the annual FSR to NIH.** See 45 CFR 74.53 and 92.42 for exceptions and qualifications to the 3-year retention requirement. 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.

If you need to get the form for filling out a FSR on Standard Form SF-269, click here. If you have a funded FIC grant or cooperative agreement and have questions about filling out the SF-269 form, you can contact Valerie Thomas, OFM, NIH at 301-402-9123.

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We welcome your questions and comments about FIC and its research programs. Please send e-mail inquiries to the **Office of Communications.** Telephone: 301-496-2075 Fax: 301-594-1211.

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SALARY CAP

(Salary Limitation)

Section 13

SALARY LIMITATION ON GRANTS, COOPERATIVE AGREEMENTS AND CONTRACTS

Release Date: January 25, 2002

NOTICE: NOT-OD-02-030

National Institutes of Health

The purpose of this notice is to provide updated information regarding the salary limitation as it relates to NIH grant and cooperative agreement awards. This information also applies to extramural research and development contract awards. The last notice in the NIH Guide for Grants and Contracts regarding the salary limitation was published January 11, 2001.

Fiscal Year (FY) 2002 is the thirteenth consecutive year for which there is a legislatively mandated provision for the limitation of salary. Specifically, the Department of Health and Human Services (HHS) Appropriation Act for FY 2002, Public Law 107-116, restricts the amount of direct salary of an individual under an NIH grant or cooperative agreement (hereafter referred to as a grant) or applicable contract to Executive Level I of the Federal Executive Pay scale. The Executive Level I annual salary rate is $161,200 for the period January 1 through December 31, 2001. Effective January 1, 2002, the Executive Level I salary level increased to $166,700.

Direct salary is exclusive of fringe benefits and facilities and administrative (F&A) expenses, also referred to as indirect costs. NIH grant/contract awards for applications/proposals that request direct salaries of individuals in excess of the applicable RATE per year will be adjusted in accordance with the legislative salary limitation and will include a notification such as the following:

According to the FY 2002 HHS Appropriations Act, "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse and Mental Health Services Administration shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level I" of the Federal Executive Pay Scale.

The term "salary" means "direct salary" which is exclusive of fringe benefits and F&A expenses. "Direct salary" has the same meaning as the term "institutional base salary." An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization.

In summary, the following reflects the time frames associated with the existing salary caps:

FY 1999 Awards (Executive Level III)

o October 1, 1998 through December 31, 1999	$125,900
o January 1, 2000 and beyond	$130,200

FY 2000 Awards (Executive Level II)

o October 1, 1999 through December 31, 1999	$136,700
o January 1, 2000 through December 31, 2000	$141,300
o January 1, 2001 and beyond	$145,100

FY 2001 Awards (Executive Level I)

o October 1, 2000 through December 31, 2000	$157,000
o January 1, 2001 through December 31, 2000	$161,200
o January 1, 2002 and beyond	$166,700

FY 2002 Awards (Executive Level I)

o October 1, 2001 through December 31, 2001	$161,200
o January 1, 2002 and beyond	$166,700

The following are examples of the adjustments that NIH will make when salaries exceed the current salary limitation:

EXAMPLE 1. INDIVIDUAL WITH FULL-TIME APPOINTMENT (based on grant award/contract issued after January 1, 2002 with a $166,700 salary limitation)

Individual's institutional base salary for a FULL-TIME (twelve month) appointment	$175,000
Research effort requested in application/proposal - 50%	
Direct Salary requested	$ 87,500
Fringe benefits requested (25% of salary)	$ 21,875
Subtotal	$ 109,375
Applicant organization's F&A (indirect) costs at a rate of 45% of subtotal	$ 49,219
Amount requested - salary plus fringe benefits plus associated F&A (indirect) costs	$ 158,594

If a grant/contract is to be funded, the amount included for the above individual will be calculated as follows:

Direct salary - restricted to a RATE of	$166,700
multiplied by effort (50%) to be devoted to project	$ 83,350
Fringe benefits (25% of allowable salary)	$ 20,838
Subtotal	$104,188
Associated F&A (indirect) costs at 45% of subtotal	$ 46,885
Total amount to be awarded due to salary limitation	$151,073
Amount of reduction due to salary limitation ($158,594 requested minus $151,073 awarded)	$ 7,521

EXAMPLE 2. INDIVIDUAL WITH HALF-TIME APPOINTMENT (based on a grant award/contract issued after January 1, 2002 with a $166,700 salary limitation)

Individual's institutional base salary for a HALF-TIME appointment (50% of a full-time twelve month appointment)	$ 87,500
Research effort requested in application/proposal 30%	
Direct Salary requested	$ 26,250
Fringe benefits requested (25% of salary)	$ 6,563
Subtotal	$ 32,813
Applicant organization's F&A (indirect) costs at a rate	

of 45% of subtotal	$ 14,766
Amount requested - salary plus fringe benefits plus associated F&A (indirect) costs	$ 47,579

If a grant/contract is to be funded, the amount included in the award for the above individual will be calculated as follows:

Direct salary - restricted to a RATE of	$ 83,350
multiplied by 50% appointment by 30% effort to be devoted to project	$ 25,005
Fringe benefits (25% of allowable salary)	$ 6,251
Subtotal	$ 31,256
Associated F&A (indirect) cost at 45% of subtotal	$ 14,065
Total amount to be awarded due to salary limitation	$ 45,321
Amount of reduction due to salary limitation ($47,579 requested minus $45,321 awarded)	$ 2,258

EXAMPLE 3. INDIVIDUAL WITH NINE MONTH APPOINTMENT (based on a contract award/grant issued after January 1, 2002 with a $166,700 salary limitation)

Individual's institutional base salary WITH NINE MONTH appointment	$131,250
Research effort requested in application/proposal 50%	
Direct Salary requested	$ 65,625
Fringe benefits requested (25% of salary)	$ 16,406
Subtotal	$ 82,031
Applicant organization's F&A (indirect) costs at a rate of 45% of subtotal	$ 36,914
Amount requested - salary plus fringe benefits plus associated F&A (indirect) costs	$118,945

If a contract/grant is to be funded, the amount included in the award for the above individual will be calculated as follows:

Direct salary - restricted to a RATE of $166,700 (annual rate) divided by 12 months	
multiplied by 9 months by 50% effort to be devoted to project	$ 62,512
Fringe benefits (25% of allowable salary)	$ 15,628
Subtotal	$ 78,140
Associated F&A (indirect) cost at 45% of subtotal	$ 35,163
Total amount to be awarded due to salary limitation	$113,303
Amount of reduction due to salary limitation ($118,945 requested minus $113,303 awarded)	$ 5,642

NOTE: If a faculty member with a 9 month appointment works during his/her off months, the monthly salary rate limitation is $13,892

($166,700 divided by 12 months) multiplied by the proposed percent of effort during those months.

Implementation of new salary limitation:

o No adjustments will be made to modular grant applications/awards or to previously established commitment levels for non-competing grant awards issued with FY 2002 funds.

o NIH competing grant awards with categorical budgets reflecting salary levels at or above the new cap(s) issued in FY 2002 will reflect adjustments to the current and all future years so that no funds are awarded or committed for salaries over the limitation.

o For awards issued with FY 2001 funds, if adequate funds are available in active FY 2001 awards, and if the salary cap increase is consistent with the institutional base salary, grantees may rebudget to accommodate these salary levels and contractors may bill at the higher level. However, no additional funds will be provided to the FY 2001 grant award and the total estimated cost of the contract will not be modified.

o An individual's base salary, per se, is NOT constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to NIH grants and contracts. An institution may supplement an individual's salary with non-federal funds.

o The salary limitation does NOT apply to payments made to consultants under an NIH grant or contract although, as with all costs, such payments must meet the test of reasonableness and be consistent with institutional policy.

o The salary limitation provision DOES apply to subawards/subcontracts for substantive work under an NIH grant or contract.

o COMPETING grant applications and contract proposals that include a categorical breakdown in the budget figures/business proposal should continue to reflect the actual institutional base salary of all individuals for whom reimbursement is requested. In lieu of actual base salary, however, applicants/offerors may elect to provide an explanation indicating that actual institutional base salary exceeds the current salary limitation. When this information is provided, NIH staff will make necessary adjustments to requested salaries prior to award.

Questions & Answers

1. Can I rebudget grant funds or bill contracts issued with FY 2002 funds to allow for the increase? Yes, provided funds are available and the increase is warranted. Prorated figures should be used for the applicable months, i.e., the $166,700 level is effective beginning January 1, 2002.

2. If a grant award (competing or non-competing) has already been issued in FY 2002, will an adjustment be made? No adjustments will be made; however, rebudgeting is allowable.

3. If an application/proposal fails to provide needed salary information, will an adjustment be made based on the new rates? No adjustment will be made if an application fails to provide adequate information regarding the individual's salary level.

4. Does the NIH appropriation language link the salary cap to a Federal Executive Level or to a dollar level? The link is to the Federal Executive Level pay scale (i.e., Executive Level III for FY 1999 and Executive Level II for FY 2000 and Executive Level I for 2001 and 2002). As the cap is linked to Federal Executive Levels, can grantees/contractors with ongoing awards rebudget/bill up to the various salary caps, based on the fiscal year of the award and the time of the salary expense? Yes, salary may be charged in accordance with the prevailing FY cap(s), as long as the levels are consistent with the individual's institutional base pay.

5. Will grantees be permitted to submit revised budgets reflecting higher base salaries? Not as a general rule. NIH policy states that grantees should always reflect actual base salaries in the requested budgets or provide an explanation indicating that actual institutional base salary exceeds the current salary limitation. As a general rule, NIH will use the information available in the existing application and make adjustments for salary cap based on information available at the time of award.

INQUIRIES

Questions concerning this notice or other policies relating to grants or contracts should be directed to the grants management or contracts management office in the appropriate NIH Institute or Center.

Return to Volume Index

Return to NIH Guide Main Index

OTHER SUPPORT INFORMATION EXAMPLE

OTHER SUPPORT INCLUDES ALL FINANCIAL RESOURCES, WHETHER FEDERAL, NON-FEDERAL, COMMERCIAL OR INSTITUTIONAL, AVAILABLE IN DIRECT SUPPORT OF AN INDIVIDUAL'S RESEARCH ENDEAVORS, INCLUDING BUT NOT LIMITED TO RESEARCH GRANTS, COOPERATIVE AGREEMENTS, CONTRACTS, AND/OR INSTITUTIONAL AWARDS. TRAINING AWARDS (T32 & T35 MECHANISMS), PRIZES, OR GIFTS ARE NOT INCLUDED.

DO NOT SUBMIT UNLESS REQUESTED

OTHER SUPPORT

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. ***Include the principal investigator's name at the top and number consecutively with the rest of the application.*** The sample is intended to provide guidance regarding the type and extent of information requested. Refer to the specific instructions in Section I. For information pertaining to the use of and policy for other support, see "Policy and Additional Guidance."

Format

NAME OF INDIVIDUAL ACTIVE/PENDING		
Project Number (Principal Investigator) Source Title of Project *(or Subproject)* The major goals of this project are...	Dates of Approved/Proposed Project Annual Direct Costs	Percent Effort

OVERLAP *(summarized for each individual)*

Samples

ANDERSON, R.R.

ACTIVE

2 R01 HL 00000-13 (Anderson) 3/1/1997 – 2/28/2002 30%
NIH/NHLBI $186,529
Chloride and Sodium Transport in Airway Epithelial Cells

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) 4/1/1994 – 3/31/2002 10%
NIH/NHLBI $122,717
Ion Transport in Lungs

The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

R000 (Anderson) 9/1/1996 – 8/31/2002 10%
Cystic Fibrosis Foundation $43,123
Gene Transfer of CFTR to the Airway Epithelium

The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING

DCB 950000 (Anderson) 12/01/2002 – 11/30/2004 20%
National Science Foundation $82,163
Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

OVERLAP

DO NOT SUBMIT UNLESS REQUESTED

OTHER SUPPORT *(continued)*

RICHARDS, L.
NONE

HERNANDEZ, M.
ACTIVE

5 R01 CA 00000-07 (Hernandez) 4/1/1995 – 3/31/2002 40% academic
NIH/NCI
Gene Therapy for Small Cell Lung Carcinoma

The major goals of this project are to use viral strategies to express the normal p53 gene in human SCLC cell lines and to study the effect on growth and invasiveness of the lines.

5 P01 CA 00000-03 (Chen) 7/1/2000 – 6/30/2002 20% academic
NIH/NCI $104,428 (sub only) 100% summer
Mutations in p53 in Progression of Small Cell Lung Carcinoma

The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor progression and metastasis.

BE 00000 (Hernandez) 9/1/1996 – 8/31/2002 20% academic
American Cancer Society $86,732
p53 Mutations in Breast Cancer

The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

OVERLAP

Potential commitment overlap for Dr. Hernandez between 5 R01 CA 00000-07 and the application under consideration. If the application under consideration is funded with Dr. Hernandez committed at 30 percent effort, Dr. Hernandez will request approval to reduce her effort on the NCI grant.

BENNETT, P.
ACTIVE

Investigator Award (Bennett) 9/1/1999 – 8/31/2002 70%
Howard Hughes Medical Institute $581,317
Gene Cloning and Targeting for Neurological Disease Genes

This award supports the PI's program to map and clone the gene(s) implicated in the development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP

None

PUBLIC POLICY REQUIREMENTS

INFORMATION ON FINANCIAL CONFLICT OF INTEREST DEBARKMENT & SUSPENSION, LOBBYING CIVIL RIGHTS, RESEARCH MISCONDUCT, NON-DELIQUENCY ON FEDERAL DEBT, STEM CELL RESEARCH, RESEARCH ON HUMAN FETAL TISSUE & HUMAN SUBJECTS

Section 15

Financial Conflict of Interest

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 PHS Funding is Sought." That subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator. These requirements do not apply to 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 the CGMO the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 identified by the organization;
- When informing the CGMO that a financial conflict of interest has been identified, the organization will assure that the interest has been addressed in accordance with the regulations by indicating whether the conflict has either been managed, reduced, or eliminated;
- The organization will continue to make similar reports on subsequently identified conflicts; and
- The organization will make additional information available to NIH, upon request, as to how identified conflicting interests have been handled in accordance with the regulations.

As described in the regulations, examples of how financial conflicts of interest might be addressed include the following:

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

Grantees also must ensure that consortium agreements address whether the consortium participant's employees will be subject to the financial conflict of interest requirements of the collaborating organization or to those of the grantee (see "Consortium Agreements").

The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing, and reporting data. Although there is no regulatory requirement for Institutional Review Boards (IRBs) to consider investigator financial conflict of interest, in some cases IRBs are incorporating conflict of interest issues in their deliberations (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects.")

Some strategies used by IRBs to consider investigator conflict of interest include the following:

- Make IRBs aware of the organization's conflict of interest policies and procedures and elect to include a statement in the informed consent form that all clinical investigators comply with the organizational guidelines.

- Ask investigators to complete a short questionnaire in which they are asked whether they or any person responsible for the design, conduct, or reporting of research have an economic interest in, or acts as an officer or a director of any outside entity whose financial interest could reasonably appear to be affected by, the research.

- Provide instruction to IRB members during their orientation on how to identify and respond to a perceived financial, academic, or other conflict of interest.

Debarment and Suspension

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

- Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

- Have not, within the 3-year period preceding the application, been convicted of, or had a civil judgment rendered against them for, 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;

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

- 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.

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

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

Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the authorized organizational 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.orcbs.msu.edu/biological/BMBL/BMBL-1.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. These regulations are available at http://www.osha.gov/comp-links.html.

- *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; or on-line at http://books.nap.edu/catalog/4911.html (ISBN)-309-05229-7).

- 42 CFR Part 72, *Interstate Shipment of Etiological Agents,* and, in particular, 42 CFR 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 applicable 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

Grantees are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedule of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812. This limitation does not apply if 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").

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, which are not subject to this prohibition.

Applicants for NIH awards with total costs expected to exceed $100,000 are required to certify that (1) they have not made, and will not make, such a prohibited payment, (2) they will be responsible for reporting the use of non-appropriated funds for such purposes, and (3) 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 organizational official on the application serves as the required certification of compliance for the applicant organization. Disclosure reporting is addressed in "Administrative Requirements—Monitoring—Reporting."

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

Research Misconduct

The grantee will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. 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 research misconduct. The signature of the authorized organizational official on the application certifies that the organization has established administrative policies as required by 42 CFR 50, Subpart A, and will comply with those policies and the requirements of the regulations. The regulations are available from the Office of Research Integrity (ORI) on its home page (http://www.ori.dhhs.gov) and, in hard copy, at the address shown in Part III.

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 research misconduct has been found or where a research misconduct inves-

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

If a misconduct investigation has been initiated, the grantee must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project(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 research misconduct 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 research misconduct.

The grantee is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. When a finding of research misconduct has been made regarding conduct by an individual(s) working on an NIH grant-supported project, whether at the grantee organization or at a third-party organization, the grantee must assess the effect of that finding on the ability to continue that project, as originally approved by NIH, and must promptly obtain NIH approval of any intended change of PI or other key personnel. A finding of research misconduct 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."

Where the validity or reliability of data has been affected by research misconduct, 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. ORI or NIH may require corrections or retractions. 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 III).

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. NIH cannot award a grant unless the authorized organizational official of the applicant organization (or individual in the case of an Individual National Research Service Award) certifies, by means of his/her signature on the application, that the organization is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal Government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the

debt is repaid or satisfactory arrangements made, NIH will 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 Molecules

Scope and Applicability

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (the NIH Guidelines) (65 FR 60328, October 10, 2000 or latest revision) apply to all NIH-funded and non-NIH funded gene transfer projects that are conducted at or sponsored by an organization that receives NIH support for recombinant DNA research. A copy of the NIH Guidelines is available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html. As defined by the NIH Guidelines, recombinant DNA molecules are either (1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) DNA molecules that result from the replication of those described in (1). The NIH Guidelines apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the NIH Guidelines. Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funds for recombinant DNA research at the organization or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization. Two specific requirements of the NIH Guidelines are discussed below, but the NIH Guidelines should be carefully reviewed, in their entirety, to ensure compliance with all of the requirements for the conduct of projects involving recombinant DNA techniques.

Institutional Biosafety Committee

Each organization that conducts research involving recombinant DNA, including contractors under grants, must have policies and procedures to ensure compliance with the NIH Guidelines and must establish a standing Institutional Biosafety Committee (IBC). The IBC is required to review each proposed project for recombinant DNA experiments and certify that the procedures, project, personnel, and facilities are adequate and in compliance with the NIH Guidelines. The composition requirements of IBCs are specified in section IV of the Guidelines. A roster of the members of the IBC must be submitted to the Office Biotechnology Activities (OBA), NIH (see Part III for address). At a minimum, the roster should include the names, addresses, occupations, and qualifications of the chairperson and members of the committee. Section IV of the NIH Guidelines specifies the roles and responsibilities of PIs and grantees in relation to IBCs and in other areas.

Serious Adverse Event Reporting

The NIH Guidelines currently require the immediate reporting of serious adverse events that occur in human gene transfer clinical studies. As specified in Appendix M-I-C-4, investigators that have received authorization from the Food and Drug Administration (FDA) to initiate a human gene transfer research protocol must report any serious adverse event immediately to the local IRB (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects—Assurance Requirements and Institutional Review Boards"), the IBC, the Office for Human Research Protections (OHRP) (if applicable), and OBA (at the address specified in Part III of this policy statement), followed by the filing of a written report with each office/group[7]. The Guidelines, available from OBA, should be consulted for complete requirements for the conduct of projects involving recombinant DNA techniques.

Human Pluripotent Stem Cell Research

NIH will fund research using human pluripotent stem cells derived from human embryos (technically known as human embryonic stem cells) or human fetal tissue (technically known as human embryonic germ cells). NIH published final *NIH Guidelines for Research Using Human Pluripotent Stem Cells* (Guidelines) that were effective on August 25, 2000. Because the Guidelines contained a few incorrect citations and other minor errors, they were corrected on November 21, 2000 (http://www.nih.gov/news/stemcell/stemcellguidelines.htm). The Guidelines establish procedures to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner. Such research also is subject to the informed consent requirements of section 498A of the PHS Act.

NIH Guidelines for Research Using Human Pluripotent Stem Cells

For purposes of the Guidelines, human pluripotent stem cells are cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not in themselves embryos. NIH research funded under these Guidelines will involve human pluripotent stem cells derived: (1) from human fetal tissue, or (2) from human embryos that are the result of *in vitro* fertilization, are in excess of clinical need, and have not reached the stage at which the mesoderm is formed. NIH funds may not be used to derive human pluripotent stem cells from human embryos. The Guidelines designate certain areas of human pluripotent stem cell research as ineligible for NIH funding.

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[7] The scope and timing of this and other safety reporting requirements is under review. The OBA Home Page (http://www4.od.nih.gov/oba/) should be consulted for developments that may affect the timing of submission of safety reports.

Human Pluripotent Stem Cell Review Group

The approval process for NIH research proposed for support under grants and cooperative agreements is described at http://www.nih.gov/news/stemcell/NOT-OD-00-050.html. In addition to the peer review process described in Part I of this policy statement, research that proposes to use human pluripotent stem cells will undergo a formal review of documentation of compliance with the Guidelines. This latter review will be conducted by the Human Pluripotent Stem Cell Review Group (HPSCRG), which is a working group of the Center for Scientific Review Advisory Council (CSRAC). The process for documenting compliance with the Guidelines is separate from the grant and cooperative agreement scientific review process. The two processes will take place in parallel in order to ensure that all aspects of scientific review and review of compliance are considered in a timely manner. Organizations and investigators proposing research using human pluripotent stem cells must be mindful of the requirements and deadlines for both processes in order to avoid delays in the potential funding of proposed research. NIH will not provide funds or allow existing funds to be used for research involving human pluripotent stem cells derived from human embryos or human fetal tissue until appropriate approvals have been obtained. Evidence of compliance with the Guidelines does not affect the peer review of the application nor does it ensure a favorable funding decision by NIH. The documentation requirements and approval process also apply to requests to conduct research using human pluripotent stem cells that are not part of a competitive process, i.e., that are part of an administrative supplemental request or a prior approval request for a change in scope.

When the HPSCRG receives compliance documentation in support of a request that proposes use of a the line of human pluripotent stem cells that has not been previously reviewed by the HPSCRG and recommended to, and approved by, the CSRAC, the HPSCRG review will take place in a public meeting. Thus, although the HPSCRG will review all requests for funds, the review of compliance documentation for the use of a cell line previously approved by NIH will not take place in a public meeting of the HPSCRG. The final approval of documentation of compliance always will take place in a public meeting of the CSRAC. Meetings of the CSRAC are open to the public. Following meetings of the CSRAC, the NIH Office of Science Policy will convey the results of the human pluripotent stem cell compliance review to the principal investigator, the organization, and the potential funding IC.

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 (1) exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, and (2) 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 subsection 498 (a) and (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 subsections 498 (a) and (b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

Research on Human Fetal Tissue

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definitions does not include established human fetal cell lines.

NIH Guidance for Research on Human Fetal Tissue

NIH has issued guidance for grantees conducting research on human fetal tissue. The guidance and other information on the governing federal statute, Sections 498A and 498B of the Public Health Service Act, 42 USC 289g-1 and 298g-2, are available on the NIH web site at http://grants.nih.gov/grants/guide/notice-files/not93-235.html
The scientific and ethical challenges associated with research utilizing human fetal tissues make it imperative that researchers and their institutions be clearly aware of and in compliance with the federal requirements particularly section 498B. Violation of this statute carries criminal penalties that are applicable to both the suppliers and the acquirers of human fetal tissue for valuable consideration.

When an application involving human fetal tissue research is submitted to the NIH, the authorized institutional official certifies (by signing the face page) that researchers using these tissues are in compliance with Sec 498B of the Public Health Service Act, 42 U.S.C. 289g-2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to

profit, and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control or transportation of these tissues.

There are additional legal requirements for research on the transplantation of human fetal tissue for therapeutic purposes that is conducted or supported by the NIH. (See Sec 498A and Sec 498B(b) of the Public Health Service Act.) Under section 498A the institutional official who signs the application must certify that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the tissue is being donated for therapeutic transplantation research, that the donation is being made without any restriction regarding the identity of individuals who may receive the transplantation, and that the donation is being made without the donor knowing the identity of the recipient.

- The attending physician must sign a statement that the tissue has been obtained in accordance with the donor's signed statement and that full disclosure has been provided to the donor with regard to the physician's intent, if any, in the research to be conducted with the tissue, and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks of the type that are associated with the woman's medical care. In the case of tissue obtained pursuant to an induced abortion, the physician's statement must also state that the woman's consent for the abortion was obtained prior to requesting or obtaining consent for the tissue to be used; no alterations of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue for research; and the abortion was performed in accordance with applicable State and local law.

- The principal investigator must sign a statement certifying that he or she is aware that the tissue is human fetal tissue obtained pursuant to a spontaneous or induced abortion, or pursuant to a stillbirth, that is being donated for research purposes. The principal investigator must also certify that: this information has been shared with others who have responsibilities regarding the research; and prior to eliciting informed consent from the transplantation recipient, the researcher will obtain written acknowledgement that the patient is aware of the aforementioned information. Moreover, the principal investigator will certify in writing that he or she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy that were made solely for the purposes of the research.

- Research involving the transplantation of human fetal tissue must be conducted in accord with applicable State and local law.

The institutional official must certify that the physician's statement, statement of the researcher, and the acknowledgement of the transplantation recipient will be available for audit by the Secretary, DHHS, or designee.

Confidentiality

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

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.

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 also is 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. Under the governing regulations, a grantee may not conduct research involving human subjects or expend Federal funds for research involving human subjects at any site, domestic or foreign, unless it has an Office for Human Research Protections (OHRP)-approved assurance of compliance with the requirements of 45 CFR Part 46 and the research has been approved by an Institutional Review Board (IRB) in accordance with the requirements of 45 CFR Part 46. 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.) OHRP should be consulted if there is any question concerning the classification of research as exempt or nonexempt.

Assurance Requirements and Institutional Review Boards

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 Human Research Protections (OHRP) 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 additional performance sites for the grant-supported research also must file an Assurance. OHRP is responsible for negotiating and approving the Assurance. Previously OHRP (and its predecessor organization—the Office for Protection from Research Risks) negotiated several types of assurances, e.g., a Multiple Project Assurance (MPA) or a Single Project Assurance (SPA) as well as an Inter-Institutional Amendment if employees of an organization with an MPA routinely conducted their grant-supported research at an affiliated institution, thereby avoiding the need for an SPA for each separate project performed at such sites.

OHRP is now negotiating Federalwide Assurances (FWA) covering all of an organization's federally supported research activities involving human subjects. Therefore, for organizations proposing research involving human subjects and not currently holding an approved assurance(s), OHRP will negotiate an FWA. Under the new system, each legally separate entity must file its own FWA even if the organization does not operate its own IRB and designates another IRB (registered with OHRP and agreeing to the designation) for that purpose. Organizations currently operating under SPAs, MPAs and/or other Assurances will continue to operate under the terms of their current assurances, including time of submission of certification of IRB review, until converted to an FWA[8]. Detailed information concerning FWAs, including the OHRP Assurance Training Module, are available on the OHRP web site.

NIH will not award a grant in which human subjects are involved for non-exempt research unless the grantee has an OHRP-approved assurance and the grantee provides a certification to NIH that the research has been approved by an appropriate IRB, consistent with 45 CFR Part 46, within 12 months prior to the budget period start date. IRB approval is not required prior to NIH peer review of an application. Therefore, following peer review and notification of priority score/percentile, applicant organizations should proceed with IRB review for those applications that have not yet received IRB approval and that appear to be in a fundable range. Regardless of when the IRB review occurs, the IRB should ensure that the research described in the application is consistent with any corresponding protocols reviewed and approved by the IRB. It is the grantee organization's responsibility to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved assurance and IRB approval of the research consistent with 45 CFR Part 46, and to comply with NIH prior approval requirements related to the addition of sites not included in the approved application (see "Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements"). The list of organizations with

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[8] After February 28, 2001 OHRP will no longer routinely accept assurances that are limited to HHS-supported research, to special categories of research, or to individual research projects. Current MPAs will remain in effect until the designated expiration date or December 31, 2003, whichever comes first; however, MPA organizations may file a new FWA at any time prior to that date and they are encouraged to do so as soon as possible. MPAs that have been administratively extended by OHRP must be replaced with an FWA no later than March 1, 2001. OHRP will not accept changes to existing MPAs (except for IRB membership updates). If changes are necessary, the organization should file an FWA.

approved assurances is available at the OHRP web site (http://ohrp.osophs.dhhs.gov). **Grantees may not draw funds from the payment system or make obligations against Federal funds for research involving human subjects at any site engaged in non-exempt research for any period not covered by both an OHRP-approved assurance and an IRB approval consistent with 45 CFR Part 46.** 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.

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

The regulations specify additional protections for research involving 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 OHRP.

Information concerning the preparation and negotiation of Assurances, as well as copies of the regulation, may be obtained from OHRP at the address shown in Part III or from its home page at

http://ohrp.osophs.dhhs.gov. OHRP also has produced a publication available through the Government Printing Office[9] and an instructional videotape.

Education in the Protection of Human Research Participants

Before funds are awarded for competing applications involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research. Key personnel include all individuals responsible for the design or conduct of the study. The description of education should be part of a cover letter that accompanies the description of "other support," IRB approval, and other information submitted prior to funding in accordance with "just-in-time" procedures. For non-competing continuations, the description of education should be part of the documentation submitted as a prerequisite to award (whether under the Streamlined Noncompeting Award Process or submitting a full non-competing continuation application).

Data and Safety Monitoring

NIH requires oversight and monitoring of all human intervention studies to ensure the safety of participants and the validity and integrity of the data. This policy is in addition to any monitoring requirements imposed by 45 CFR Part 46 (see "Human Subjects" in this subsection), FDA, or the *NIH Guidelines for Research Involving Recombinant DNA Activities.* The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. Oversight and monitoring under Phase III clinical trials should be in the form of Data Safety Monitoring Boards (DSMBs). A DSMB also may be appropriate for Phase I and II clinical trials if the studies have multiple clinical sites, are blinded (masked), or employ particularly high-risk or vulnerable populations. The DSMB monitoring function is above and beyond that traditionally provided by IRBs; however, the IRB must be cognizant of the procedures used by DSMBs, and the DSMBs must provide periodic reports to investigators for transmittal to the local IRB.

For competing research applications involving Phase I or II clinical trials, the applicant must include a general description of the data safety monitoring for review by the Scientific Review Group. A detailed monitoring plan must be included as part of the research protocol, be submitted to the local IRB, and be reviewed and approved by the funding IC prior to initiation of the trial. At a minimum, monitoring plans must include a description of the reporting mechanisms for advising the IRB, FDA, and NIH of adverse events. In specific cases where the funding IC is the sponsor of the test agent, i.e., the holder of the Investigational New Drug Application, investigators must submit individual adverse event reports to the IC in accordance with FDA regulations. If a safety monitoring committee has been established for Phase I or II trial, summary reports of the committee's discussions must be submitted to the IC and to the IRB. The funding IC may specify the reporting requirements for adverse events, which are in addition to annual report to the IRB.

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[9] *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 OHRP's Web site (http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm).

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

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

Further information concerning these requirements is contained in several *NIH Guide for Grants and Contracts* notices (http://grants.nih.gov/grants/guide/notice-files/not98-084.html) and (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html).

Investigational New Drug Applications/Investigational Device Exceptions

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 to be eligible for funding. As provided in the FDA regulations, an IND or Investigational Device Exception (IDE) also may apply to biologics or devices. The FDA regulations are published at 21 CFR Parts 50 and 312.

The official sponsor of the IND/IDE, whether NIH, a grantee, or a third party, is legally responsible for meeting the FDA requirements. If a third party, such as a pharmaceutical company or research organization under contract to a grantee or to a pharmaceutical company, is the IND/IDE sponsor, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the sponsor rather than the grantee. This generally will be the case for larger, multi-site clinical trials. If the grantee is the IND/IDE holder, commonly referred to as an "investigator-initiated IND/IDE," the grantee or the investigator serves as the sponsor and assumes the legal responsibility. In any case, the grantee is ultimately responsible to NIH for ensuring compliance with the requirements for protection of human subjects, including compliance with FDA's requirements.

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

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

FREQUENTLY ASKED QUESTIONS

Section 16

Frequently Asked Questions

If a foreign or international grantee is issued a Notice of Grant Award, which signifies that the grant is funded, how do they get the grant funds?

Foreign/International grants will normally be paid by U.S. Treasury check by the National Institutes of Health (NIH) Office of Financial Management (OFM) on a predetermined quarterly advance basis, usually in four equal installments. The contact person at NIH, OFM who processes these payments is Ms. Joyce Lee who can be reached at 301-402-5798.

What assurances and certifications are required for a foreign organization?

The following assurances and certifications are required for grants to foreign organizations:

- Human Subjects (if applicable)
- Vertebrate Animals (if applicable)
- Research Misconduct
- Lobbying & Drug-Free Workplace
- Delinquent Federal Debt
- Financial Conflict of Interest Debarment (with the exception of foreign governments and international organizations)

You can find out more information about these assurances by referencing the NIH Grants Policy Statement at:
http://grants1.nih.gov/grants/policy/nihgps_2001/part_iia_1.htm

What is the NIH policy concerning the transfer of a grant to or between foreign institutions?

A change of grantee that involves the transfer of a grant to or between foreign institutions or international organizations is possible but will require a single case deviation from policy by the appropriate NIH Institute or Center's Chief Grants Management Officer and approval of the Institute or Center Advisory Council/Board. Transfer of a grant from a foreign organization to a domestic organization requires the approval of the Grants Management Officer.

Can requests for funding be made in foreign currency and then be converted to U.S. dollars?

No. All requests for funds, including the budget contained in the application, must be stated in U.S. dollars. Once an award is made, the NIH will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental

awards.

Do foreign grantees with grants under the Streamlined Non-competing Application Process (SNAP) have to submit Financial Status Reports for each budget period?

Yes, Financial Status Reports (FSRs) must be submitted for each budget period on Standard Form SF-269. The SF-269 form can be found at: http://grants.nih.gov/grants/fsr_sf269_long.pdf.

How to do I complete the budget pages for a D43 Competing Grant Application?

Please follow the instructions for the revised PHS 398. The instructions may be found at: http://grants.nih.gov/grants/funding/phs398/section_1.html#4_detailed

DO NOT use the Modular Budget Format Page.

All budget items related to faculty and administrative participation in the program should be itemized on PHS 398 Form Page 4. For the entire proposed project period, use PHS 398 Form Page 5. Please note:

- The salary limit for U.S. faculty is currently $166,700. Further information can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-030.html
- List foreign site staff under the "Consultants" category. Do not include them under the "Personnel" category, or under "Stipends" on PHS 398 National Research Service Award (NRSA) Substitute Form Page 4.
- Please include all **faculty** travel (U.S. and foreign) under the "Travel" category on PHS 398 Form Page 4, reserving all **trainee** travel expenses to be listed on NRSA Substitute Form Page 4.
- A separate, detailed budget for subcontracts/consortiums should be completed on separate PHS 398 Form Pages 4 and 5, and the total costs reflected under "Consortium/Contractual Costs" on the parent budget page PHS 398 Form Page 4.

The total direct costs from PHS 398 Form Page 4 should be summarized as an item on NRSA Substitute Form Page 4 in the "Other" category, and identified as "Totals from PHS 398 Form Page 4 and 5." This will result in NRSA Substitute Form Pages 4 and 5 reflecting the composite budget, showing all funds requested. All budget items related to **trainee** participation should be itemized on PHS 398 NRSA Substitute Form Page 4. For the entire proposed project period, use NRSA Substitute Form Page 5.

We welcome your questions and comments about FIC and its research programs. Please send e-mail inquiries to the **Office of Communications.** Telephone: 301-496-2075 Fax: 301-594-1211.

TOP

Office of Communications • Fogarty International Center • National Institutes of Health
Building 31, Room B2C29 • 31 CENTER DR MSC 2220
Bethesda, MD 20892-2220

TRAVEL

(Sample Policy)

Section 17

Policy:	Travel Policy
ssue Date:	December 18, 1995
Last Revision Date:	November 17, 1997

SAMPLE

Purpose

From time to time [redacted] employees are required to travel on behalf of the company for business purposes. This policy sets forth procedures and guidelines for incurring expenses and for their reimbursement. If you are uncertain about a particular expense or policy, contact your supervisor prior to the expenditure. Please note that SBIR related travel requires special attention in regard to hotel per diems.

Authorization to Travel

All marketing related travel must be approved in advance by [redacted]. Any other out of town trips requiring an overnight stay must be approved in advance by [redacted]. Please complete a Purchase Order for the necessary travel arrangements and accommodations.

Use of Personal Auto

From time to time, it may be necessary for you to utilize your vehicle for pre-authorized company business. You may claim 31.5 cents per mile as mileage reimbursement.

Air Fare

Airline tickets should be booked in advance in order to take advantage of any discounts. Please bear in mind that discount fares do not allow changes, so you must be able to make a commitment to the travel dates and change them only under extraordinary circumstances. Travel and accommodations associated with marketing exhibits/tradeshows should be coordinated through [redacted] Other travel and accommodations should be coordinated through [redacted]. All air travel must be coach class. Please include your airfare receipt with your expense statement.

Auto Rental

Auto rental requires the prior approval of your department manager. In general, auto rentals will be approved for a group traveling together. Include your rental receipt with your expense statement.

Taxi and Other Transportation Costs

Please utilize shuttle/hotel bus service whenever possible. When traveling in groups taxis may be economical. When traveling to and from your local airport, choose between long-term parking or a taxi based on whichever is the most economical for the company. Obtain receipts whenever possible and include them with your expense statement

Hotel

Hotels accommodations for exhibit activities will be arranged for the group attending. Coordinate your stay through [redacted]. For other business trips choose hotels convenient to your business activities. Bear in mind that if you are on SBIR related travel, your grant will only cover lodging expenses up to the government approved lodging per diem rate for that city. See *http://policyworks.gov/org/main/mt/homepage/mtt/perdiem/travel.shtml* to find the government approved lodging per diem rate for the city to which you are traveling. If necessary, you can still stay in a hotel that charges a higher rate than the government lodging per diem, but [redacted] will have to pay the difference. Hotel rates in excess of $100.00 per night must be pre-authorized by [redacted] or [redacted], depending on

the type of travel. Please supply copies of all hotel receipts with your expense statement and also remember to report phone calls and faxes separately. Movies, room service, shoe shine, etc. are considered incidental expenses and must be covered by the meal per diem.

Per Diem Meal Reimbursement

Meals will be reimbursed on a per diem basis. The per diem rate varies by travel city and ranges between $30 and $42 per day. See *http://policyworks.gov/org/main/mt/homepage/mtt/perdiem/travel.shtml* to find the government approved per diem rate for the city to which you are traveling. The per diem applies to all full travel days associated with an overnight stay. Any meal expenditures over the per diem rate will not be reimbursed by the company. Partial travel day per diem is as follows:

Leave by	Return by	Per diem
8:00 am		Full amount
11:00 am		80% of full amt
4:00 pm		50% of full amt
	11:00am	20% of full amt
	4:00 pm	50% of full amt
	after 5:00 pm	Full Amount

Entertainment Expense

Entertainment expenses require your department manager's approval. Any request for reimbursement of entertainment expenses must be accompanied by a description of the entertainment, a listing of the individuals entertained, the purpose of the entertainment and a detailed receipt for the expense. Entertainment where a disproportionate number of company employees participated will be questioned and may not be fully reimbursed. Entertainment expenses cannot be charged to SBIR grants.

Telephone/Fax/Incidental Expenses

The cost of telephone calls from hotels is expensive. Use of telephone credit cards is encouraged. Calls should be for business purposes or to keep in touch with immediate family. Please separate phone/fax expenses from hotel and report under the Phone/Fax category on your expense statement. Other incidental expenses must be covered by the meal per diem.

Saturday Night Stay Policy

In many instances travel over a Saturday can save on the price of the air fare. Up to one half of the savings may be used toward week-end accommodations, meals and miscellaneous expenses if an employee chooses to stay over the Saturday. This is not allowed if you are on SBIR related travel.

International Travel

Must be arranged by your department manager with the president of the company. International travel will involve per diems as well. You can find those on the same Internet site as well.

TIME AND EFFORT REPORTING FOR COMMERCIAL ORGANIZATIONS

(POLICY EXAMPLE)

Section 18

Time and Effort Reporting for Commercial Organizations

Policy

Commercial (for-profit) organizations must document salaries and wages charged to contracts and grants by maintaining a labor distribution system for all employees regardless of function. The labor distribution system must account for **total** hours and charge direct and indirect labor to the appropriate cost objectives in order to accurately identify labor costs:

- Charged to direct projects
- Charged to indirect activities
- Included in the base to which indirect costs are allocated.

Internal controls

Timekeeping procedures and controls on labor charges are of utmost concern. Unlike other costs, labor is not supported by external documentation or physical evidence which provides independent checks and balances. It is critical that managers indoctrinate individual employees on their independent responsibility for accurately recording their time. Internal controls over labor charging should meet the following criteria:

- The responsibility for timekeeping and payroll accounting should be separated.
- Procedures must be clear and reasonable so there is no confusion regarding the rationale for the controls or misunderstanding as to what is and is not permissible.
- Maintenance of controls must continually be verified, and violations must promptly and effectively be acted upon to serve as a deterrent to prospective violations.
- Individual employees must constantly be made aware of controls that act as an effective deterrent against violations. This awareness can be accomplished by emphasizing the importance of accurate time and effort reporting in orientation sessions, periodic meetings and the posting of messages as reminders.
- Changes on timesheets to the number of hours recorded or the cost center identified should be made by the employee **and** must be initialed by the employee.
- The company policy must state that the nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant or other factors.

- The company policy should emphasize that complete and accurate time and effort reporting is an important part of an employee's job. Careless or improper reporting may lead to disciplinary actions under company policies as well as applicable Federal statutes.

Time and Effort Documentation Requirements and Responsibilities

Detailed instructions for time documentation should be established in written company procedures. A manual system would require handwritten pen and ink entries on a paper timesheet reflecting all the days in the pay period. An automated timekeeping system typically would use remote data entry for recording labor charging data and sending it directly to a central computer for processing. Supporting documentation for an automated system would normally consist of computer printouts showing data that appear on source documents, i.e., timesheets, in a manual system.

Employee Responsibilities

Whether a manual or automated time and effort reporting system is in place, the employee is personally responsible for:

- After the fact recording of hours (or fractions thereof) on a daily basis.

- Recording all hours worked and all hours absent. All hours should be recorded whether or not they are paid.

- Recording of hours on the timesheet in ink (manual system only).

- Recording the correct distribution of hours by project or indirect category. The nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant or other factors. To ensure accuracy, a listing of project numbers/indirect categories and their descriptions should be provided in writing to each employee.

- Any changes/corrections to timesheets should be made by the employee and must show what was initially recorded, i.e., no erasures or "white out" of entries. The employee also must initial any change(s).

- At the end of each pay period, the employee must sign the timesheet or electronically certify the labor distribution in an automated system.

Supervisor Responsibilities

- An authorized company official (e.g., supervisor) must cosign timesheets or electronically certify individual time and effort reporting at the end of each pay period.

- The supervisor is prohibited from completing an employee's timesheet or entering hours in an automated system unless the employee is absent for an extended period of time on some form of authorized leave.

Time Sheet

Employee Name_____ Employee Signature_____

Supervisor Name_____ Supervisor Signature_____

MONTH:_____ **YEAR:** _____

DAY:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		TOTAL
	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
PROJECT:																	
INDIRECT*																	
VACATION																	
HOLIDAY																	
SICK LEAVE																	
OTHER																	
TOTAL																	

EMPLOYEE INSTRUCTIONS: Time Sheet must be completed in ink and corrections should be initialed by employee. For each day of the month (column) enter the number of hours worked on each project (as well as IR&D) or individual indirect category. At the end of the reporting period, sum the number of hours in the "Total" column and enter on the last line in the column. Sign and date the time sheet, and give it to your supervisor.

***Record the number of hours by indirect category (for example; overhead, G&A, Sales, Marketing etc.)**

SAMPLE EXPENSE REPORT

Section 19

Expense Rep

Name: Report Period:

Event: Place: Purpose:

Date	City and State	Lodging	For SBIR Travel Use Only Lodging: Per Diem*	For SBIR Travel Use Only Lodging: Excess	Meal Per Diem*	Entertainment & Business Meals (Itemize Below)	Transportation: Airfare/Mileage	Transportation: Car Rental/Taxi	Transportation: Parking/Tolls	Phone/ Fax	Miscellaneous (Itemize Below)	Daily Total
Totals:												

* Government approved per diem rates for the travel city. (http:\\policyworks.gov/org/main/mt/homepage/mtt/perdiem/travel.shtml)

Less Advance	
Total	

Entertainment and Business Meals

Date	Name, Company, Title of Person(s) Entertained	Business Discussed	Time and Place	Amount	% Allocated to Business

Miscellaneous Expenses

Date	Items	Amount

I hereby certify that the above is a true and accurate account of my expenses in connection with the stated company business.

Signature: Date:

Approved: Date:

SAMPLE EMPLOYEE AGREEMENT

Section 20

SBIR/STTR

Who Is an Employee?

Are you a contingency worker—a freelancer, temporary, part-timer, one-year or contract worker—or actually an employee?

"Hiring for a particular project and not paying benefits do not necessarily make workers into independent contractors," said Peter DeChiara, a New York attorney, writing in the newsletter of Working Today (212-840-6066), a nonprofit membership organization for people who work independently.

DeChiara lists these guidelines to determine if you're an employee:

- The company supervises you or controls how you do your work.
- You work on company premises.
- You've worked for the company for several years.
- You work only for that company.
- You use the company's equipment, not your own.
- The company sets the hours you work.
- You have no money invested in the company and won't profit or lose as a result of your work.

DeChiara said the IRS "estimates" that misclassification costs the federal government more than $1.5 billion in lost payroll taxes." — Knight-Ridder

EMPLOYMENT AGREEMENT

This Agreement dated is entered into between (the "Company"), with an office and principal place of business at and ("Employee").

1. Employment. The Company hereby employs Employee and Employee hereby accepts such employment and agrees to perform the services specified herein upon the terms and conditions hereinafter set forth.

2. Term. The term of this Agreement shall commence as of the date of this Agreement and continue until terminated as hereinafter set forth.

3. Compensation. For all services rendered by Employee under this Agreement the Company shall pay Employee (i) a gross salary of $ (before standard deductions) per year, payable bi-monthly during the term of this Agreement, and (ii) certain commissions as described on Annex A attached hereto and incorporated herein by reference. The compensation of Employee shall be subject to adjustment from time to time by the Board of Directors of the Company (the "Board").

4. Benefits. During the term of this Agreement, Employee shall receive the benefits provided by the Company to all full-time employees of the Company, including participation in the Company's 401K plan after 12 full months of employment with the Company. The benefits provided by the Company shall be subject to modification, adjustment or replacement, in whole or in part, from time to time by the Board, and nothing herein should be construed as a guarantee or entitlement as to the level, amount or value of such benefits.

5. Duties. Employee has been hired as a and he shall perform the duties normally incidental to that position for as long as he shall hold that position. Employee shall also perform such other duties and responsibilities as may be prescribed from time to time by the Board.

6. Limitation on Authority. Without express authorization from the Board, Employee shall not: (a) incur any debt on behalf of the Company; (b) bind the Company under any contract, agreement, note, mortgage or otherwise; (c) release or discharge any debt due the Company, unless the

Company has received the full amount thereof; or (d) sell, mortgage, transfer or otherwise dispose of any assets of the Company.

7. Extent of Service. Employee shall devote such time, attention and energy to the business of the Company as the Board shall require, and shall not during the term of this Agreement be engaged in any other business activity if pursued for gain, profit or other pecuniary advantage, without the express consent of the Board. The foregoing shall not be construed to prevent Employee from making investments in businesses or enterprises, provided such investments do not require any services on the part of Employee in the operation or affairs of such business or enterprise.

8. Disclosure of Information. Employee acknowledges that, during the course of his involvement with the Company as an employee, he will occupy a position of trust and confidence, and that, during such employment with the Company, he will have access to and become familiar with confidential and proprietary information of the Company, including, without limitation, the types of information listed on Annex B attached hereto and incorporated by reference (collectively, "Confidential Information").

Employee covenants that he will keep secret all Confidential Information and that he will not, during or after the term of this Agreement, disclose or communicate any Confidential Information, directly or indirectly, to any other person or entity, nor will Employee use any Confidential Information in any way for his own benefit, directly or indirectly, or in any way which is inconsistent with the confidential nature of Confidential Information. Upon termination of this Agreement, for whatever reason, Employee shall deliver to the Company any and all Confidential Information in his possession or control, including all records, files, notes, notebooks, reproductions and other documents of whatsoever nature relating to the Company.

9. Solicitation. Employee shall not, during or after the term of this Agreement, directly or indirectly, (a) induce any present or future customer of the Company to do business with any company which manufacturers or markets products similar to those manufactured or marketed by the Company; (b) request or advise any present or future customer of the Company to withdraw, curtail or cancel such customer's business with the Company; or (c) cause or induce any present or future employee of the Company hired during the term of this

Agreement to leave the employ of the Company or accept employment with the Employee or with any other person or entity.

10. Restrictive Covenant. Employee shall not, during the term of this Agreement and for a period of 24 months thereafter, engage, within the United States of America, as principal, agent, trustee or through the agency of any person or entity, in any business conducted by the Company or in competition with the Company, and Employee shall not become an owner of more than 1% of the outstanding shares of capital stock of any corporation, or an officer, director or employee of any corporation, or a member or employee of any partnership or an owner or employee of any other business which conducts a business in competition with the Company.

11. Proprietary Property. During the term of this Agreement, Employee shall promptly and fully disclose to the Company all inventions or improvements made or conceived by him, solely or with others. Where the subject matter of such inventions or improvements are made or conceived by Employee during the term of this Agreement or within six months thereafter and result from or are suggested by any work which Employee may do for or on behalf of the Company or relates to the Company's business, the Company shall have all rights to such inventions or improvements, whether patentable or not. At the request of the Company, either during or after the term of this Agreement, Employee shall execute or join in executing all papers or documents required for the filing of patent applications in the United States and such foreign countries as the Company may elect, and shall assign all such patent applications to the Company or its nominee, and shall provide the Company or its agents or attorneys with all reasonable assistance in the preparation and prosecution of patent applications, drawings, specifications, and the like, all at the expense of the Company, and shall do all that may be necessary to establish, protect and maintain the rights of the Company or its nominee in the inventions, patent applications, and Letters Patent in accordance with the spirit of this Agreement.

12. Involuntary Termination. This Agreement may be terminated by the Company upon written notice to Employee at anytime after the occurrence of any of the following:

(a) Employee dies;

(b) Employee fails or refuses to (i) faithfully and diligently perform his duties as set forth in this Agreement or as may from time to time be

prescribed by the Board, (ii) comply with any of the provisions of this Agreement, or (iii) comply with any policies, standards or regulations of the Company as they may from time to time be prescribed by the Board; or

(c) Employee commits dishonest acts toward the Company.

13. Voluntary Termination. Notwithstanding the foregoing, Employee acknowledges that he is employed by the Company under this Agreement as an employee "at will" for an unspecified duration, and that either Employee or the Company may terminate this Agreement, with or without cause, at any time, by giving the other party hereto written notice of termination, such termination to be effective 30 days from the date of such notice; provided, however, the Company may, in its discretion, pay Employee an amount equal to two months of Employee's salary (set forth in Section 3) in lieu of said 30-day notice and, in such event, termination shall become effective upon notice thereof by the Company to Employee.

14. Remedies. In the event of a breach or threatened breach by Employee or any of the provisions of paragraphs 8, 9, 10 or 11 of this Agreement, the Company will suffer irreparable injury not fully compensable by money damages and, therefore, will not have an adequate remedy available at law. Accordingly, if the Company institutes an action or proceeding to enforce the provisions of paragraphs 8, 9, 10 or 11 of this Agreement, the Company shall be entitled to obtain such injunctive relief or other equitable remedy from a court of competent jurisdiction as may be necessary or appropriate to prevent or curtail any such breach, threatened or actual. The foregoing shall be in addition to and without prejudice to such other rights as the Company may have under this Agreement, at law or in equity, including, without limitation, the right to sue for damages.

15. Survival. The provisions of paragraphs 8, 9, 10, 11 and 14 through 21 shall survive any termination of this Agreement.

16. Notices. Any notice given under this Agreement shall be sufficient, if in writing, and mailed by either registered or certified mail, return receipt requested, postage prepaid to the Company at its principal place of business and to Employee at his last known residence address.

17. Assignment. The rights and obligations of the Company under this Agreement shall inure to the benefit of and shall be binding upon the successors and assigns of the Company.

18. Waivers. The waiver by any party hereto of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach of any party.

19. Invalid Provisions. The invalidity or unenforceability of a particular provision of this Agreement shall not affect the other provisions hereof, and this Agreement shall be construed in all respects as if such invalid or unenforceable provisions were omitted.

20. Entire Agreement. This Agreement embodies the entire agreement between the parties hereto relating to the subject matter hereof, and supersedes and replaces in their entirety all prior understandings and agreements relating to the subject matter hereof. This Agreement may be amended or supplemented only by an instrument in writing executed jointly by Employee and an authorized officer of the Company.

21. Applicable Law. This Agreement shall be subject to and governed by the laws of the State of [redacted]. Venue for any action hereon or hereunder shall lie in [redacted] County, [redacted], and Employee hereby consents thereto.

Executed as of the date first written above.

By

President

SAMPLE CONSULTING AGREEMENT

Section 21

Sample Consultant Services Policy

Consultant Services Policy and Procedures:

The Corporation may utilize a number of consultants to help in highly specialized areas (e.g. Intellectual Property) or where it is not economical to hire a full-time person to fill a position for a short-term project. The use of consultants allows the Corporation to gain access to highly skilled professionals to assist in very specialized areas

The process for determination of need and selection process is as follows:

Step	Description	Responsible
Consulting Request	Identification of the need for outside consulting services to be used. All requests are reviewed at weekly management meeting.	Anyone in the Corporation may submit a request
Approval of Consulting	Approve request for consultant services.	President/CEO
Selection of Consultant	Selection depends on area of specialty. For scientific/research, the Chief Science Officer will make the selection. The President/CEO selects all other consultants.	President/CEO Chief Science Officer
Rates and Contract	All consultants are required to sign a consultant agreement that describes the services to be performed, the rate of payment, and terms (e.g., confidentiality) All rates are approved by the President/CEO and basis determined by regional salary scales, consultant institutional rate, or other reasonable methods.	President/CEO
Payment	Consultants must submit an invoice for services prior to payment. Rate based consultant services (e.g. hourly or daily charge), the invoice must include the time report specifying date, time, and description of work. The President/CEO, prior to payment, must approve fixed fee consultant services after review of consultant report/work performed.	President/CEO

An Example of a Typical Consulting Agreement

CONSULTING AGREEMENT

This Agreement is effective as of the ____ day of _____, 199___, by and between . Corporation, a . . corporation with its principal place of business located at
(. ") and _____
_____ ("Consultant").

WHEREAS, Consultant possesses valuable information, knowledge and technical expertise relating to_____; and

WHEREAS, desires to retain Consultant on the basis set forth in this Agreement.

NOW, THEREFORE, for good and valuable consideration, . and Consultant agree as follows:

1. OBLIGATIONS OF CONSULTANT

a. Consultant shall visit up to two (2) days per year at times mutually agreeable to Consultant and . to provide consulting services for 's _____.

b. Consultant shall be available as is reasonably necessary to , by telephone, facsimile transmission and electronic mail, to provide consulting services for _____

c. Consultant shall allow to visit Consultant's laboratory up to two (2) times per year so that may obtain consulting services from Consultant for 's _____

d Consultant shall occasionally review and critique product literature and promotional materials related to 's _____.

e. Consultant shall perform other consulting services for as agreed upon by Consultant and : in writing

2. OBLIGATIONS OF

a shall pay Consultant _____

b. shall furnish Consultant with a _____ Dollar (US $_____) product credit for products at 's US catalog list price and such credit shall be in effect during the first _____ (___) months of this Agreement only. Any credit that remains after the first . _____ (___) months of this Agreement shall revert back to Consultant shall not use any of the Promega products described herein in research

that is subject to consulting, licensing, or similar obligations to another commercial entity, unless prior written permission is obtained from by Consultant.

c. shall reimburse Consultant for all reasonable out-of-pocket expenses related to Consultant's visits to as described in Section 1a herein upon submission of an itemized statement for such expenses, but only if such expenses are authorized by prior to being incurred. Consultant shall request written authorization for intended expenses from _____ _____.

3. USE OF FACILITIES

During the term of this Agreement, agrees to allow Consultant access to and reasonable use of 's facilities, subject to the following qualifications.

a. Consultant expressly warrants and represents that they will perform their services on their own business premises and with their own equipment, except by agreement with Promega and in accordance with paragraphs 3.b. and 3.c.;

b. Consultant shall be allowed to use the facilities of for the direct benefit of .; and

c. Any use of 's facilities by Consultant shall be subordinate to . 's own requirements.

4. PROVISION OF OTHER SERVICES

During the term of this Agreement, Consultant may provide services to others, provided such provision of services will not constitute or create the possibility of a conflict with 's interests and further provided that Consultant advises of the names of all such other persons or entities and the general nature of the work to be performed by the Consultant in each case. Notwithstanding anything in this Agreement to the contrary, shall have the right to terminate this Agreement if, in its reasonable opinion, the Consultant's performance of such services will conflict with 's interests. Consultant represents that Consultant is not a party to any existing agreement that would prevent Consultant from entering into and performing under this Agreement

5. TERM/TERMINATION

a. This Agreement shall become effective upon the date first hereinabove written and shall continue in effect through _____ unless sooner terminated in accordance with the provisions of this Section. The parties hereto may, however, extend the term of this Consulting Agreement for additional periods as desired under mutually agreeable terms and conditions which the parties reduce to writing and sign. Either party may terminate this Consulting Agreement upon thirty (30) days prior written notice to the other

b. In the event that either party hereto shall commit any breach of or default of any of the terms or conditions of this Agreement, and also shall fail to remedy such default or breach within thirty (30) days after receipt of written notice thereof from the other party hereto, the party giving notice may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party pursuant to Section thirteen (13) herein.

c. Termination of this Consulting Agreement by either party for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Consulting Agreement.

6. CONFIDENTIALITY

Any and all knowledge, know-how, practices, process, or other information relating to the subject of this Consulting Agreement (hereinafter referred to as "Confidential Information") disclosed or submitted to Consultant in writing or in other tangible form which is designated as Confidential Information, shall be received and maintained by Consultant in strict confidence and shall not be disclosed to any third party. Consultant shall not use said Confidential Information for any purpose other than purposes specified in this Consulting Agreement. Consultant may disclose Confidential Information to individuals requiring access thereto for purposes of this Agreement provided, however, that prior to making any such disclosures each such individual shall be apprised of the duty and obligation to maintain the Confidential Information in strict confidence and not to use Confidential Information for any purpose other than in accordance with the terms and conditions of this Consulting Agreement. The obligations of Consultant under this Section 6 shall not apply to information: (i) which is now, or becomes in the future, public knowledge other than through acts or omissions of Consultant; (ii) which is lawfully obtained by Consultant from a third party; or (iii) which Consultant can demonstrate by written records was previously known to Consultant or was developed by Consultant without reference to Confidential Information The obligations of the parties under this Section six (6) shall survive the expiration or termination of this Consulting Agreement for a period of three (3) years thereafter.

7. PUBLICATION

Notwithstanding the undertaking of confidentiality of Section 6 above, Consultant may publish the results of Consultant's research arising out of knowledge gained from this Consulting Agreement, provided however, that Consultant agrees to submit the proposed manuscript to for its approval at least sixty (60) days prior to submission for publication If for good reason (such as confidential or proprietary information of is disclosed or a possible conflict with 's development and commercialization program) requests a modification thereof within sixty (60) days of its receipt thereof, submission for publication or disclosure will thereupon be withheld by Consultant until and Consultant agree to a revision of the proposed publication acceptable to . Approval of a manuscript for publication under this Section 7 shall be made in writing by an officer of

DRAFT

8. INTELLECTUAL PROPERTY

a. Consultant shall fully and promptly communicate to ., in writing on a form acceptable to , all inventions, improvements, devices, processes, treatments, formula, and compounds, whether patentable or not ("Inventions"), which are first conceived or first reduced to practice by Consultant, either individually or jointly with others, during the consulting relationship with Promega or within one (1) year thereafter, and which pertain to the Obligations of Consultant set forth in Section 1, above. All such Inventions shall be the sole and exclusive property of . Consultant shall and hereby does assign all of Consultant's right, title, and interest in and to such Inventions, to .

b. The provisions of Section 8.a. herein shall not apply to any Invention for which no facilities, products, equipment, Confidential Information or consulting time of was used and which was developed entirely on Consultant's own time.

c. Consultant agrees to keep and maintain adequate and current records of all Inventions, at all stages of development, in the form of notes, sketches, drawings, and reports relating thereto. All such records shall be and remain the property of . at all times. Upon termination of the consulting relationship contemplated in this Agreement, by either party, Consultant agrees to return all such records of all Inventions to and shall retain copies of such records only with 's written authorization.

d. During and after the consulting relationship with , at the request and expense of , Consultant shall assist in every way proper to obtain and to vest in title to and exclusive rights in Inventions. This provision shall include but not be limited to executing and delivering all documents necessary or desirable to accomplish such objective. Specifically, this provision shall be interpreted to mean that Consultant shall promptly review, sign and deliver to any and all requested documents or other information necessary to file and obtain patents relating to Inventions throughout the world. This provision also shall mean that if becomes involved in litigation or administrative proceedings relating to Inventions, at the request and expense of , Consultant shall cooperate and render assistance and advice thereto. If Consultant renders assistance or advice to under this Section after the termination or expiration of this Consulting Agreement, then Consultant shall be paid for services rendered at the then prevailing rate for consultants of like experience and training. Expenses incurred by Consultant in rendering services under this provision also shall be reimbursed by .

9. INSURANCE/INDEMNITY

Consultant shall maintain adequate insurance protection covering Consultant's respective activities, as well as adequate insurance coverage for vehicles. Consultant shall indemnify

and hold harmless from all liability for bodily injury, death, property damage or other costs and expenses (including reasonable attorney fees) resulting from Consultant's acts or omissions (including, without limitation, negligent acts or omissions) arising out of Consultant's activities under this Agreement.

10. ENTIRE AGREEMENT

This Consulting Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and the parties are under no obligation to one another and make no agreement with one another with respect to the subject matter hereof except as specified in this Consulting Agreement.

11. ASSIGNMENT

Consultant shall not assign or otherwise transfer any of Consultant's rights, duties or obligations under this Consulting Agreement without the prior written consent of

12. SEVERABILITY

Should any provision of this Agreement be held invalid, illegal or unenforceable, by a court of competent jurisdiction, such provision shall be considered void. All other provisions, rights and obligations shall continue without regard to such provision

13. NOTICES

All notices provided for in this Consulting Agreement shall be sent to the parties at the addresses indicated in the initial paragraph of this Consulting Agreement, unless the parties change address by written notice to the other. Any notice shall be deemed to have been given (i) when delivered in person, (ii) one business day after deposit with a nationally recognized overnight courier service, or (iii) two business days after being deposited in the United States mail postage prepaid, first class, registered or certified mail [The following language should be used for agreement with international Consultant: "Any notice shall be deemed to have been given two business days after deposit with an internationally recognized overnight courier service."]

14. RELATIONSHIP OF THE PARTIES

Consultant shall be an independent contractor with respect to . Consultant shall not be entitled to benefits or compensation from . (except as provided in Section 2 above) and shall in no event be entitled to any fringe benefits payable to employees of . Nothing in this Agreement is intended or shall be deemed to constitute a license, partnership, agency, employment, or joint venture relationship between the parties

15. MISCELLANEOUS WARRANTIES AND REPRESENTATIONS

a. Consultant expressly warrants and represents that for the duration of this Agreement, Consultant shall make Consultant's services available to the general public and will perform such services for other businesses at the same time Consultant is under contract with Promega, subject to Section four (4) of this Agreement; and

b. Consultant expressly warrants and represents that Consultant has and maintains Consultant's own business premises.

c. Consultant expressly warrants and represents that, to the best of Consultant's knowledge after reasonable inquiry, Consultant has the legal authority to enter into this Agreement without the need to obtain authorizations or approvals from any third party or parties. However, to the extent and further authorizations or approvals are needed for this Agreement to be binding and fully enforceable, Consultant agrees to obtain any and all such authorizations or approvals. If Consultant obtains approvals as set forth in the previous sentence, then Consultant agrees to provide to , prior to countersignature by , either (a) evidence of such approval(s), such as by copies of appropriate documentation or (b) completion of the "Approved" section of the signature page of this Agreement by the appropriate approving party or parties."

d. Consultant represents and warrants that, to the best of Consultant's knowledge, any present or future disclosure requirements relating to the relationship between Consultant and described by this Agreement have been and will continue to be satisfied.

16. COUNTERPARTS

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

17. GOVERNING LAW

This Consulting Agreement shall be governed, construed and enforced in accordance with the laws of the State of , excluding any choice of law principles which may direct the application of the laws of any other jurisdiction.

Intending to be legally bound, the parties hereto have signed this Agreement by their duly authorized representatives. Any facsimile transmission of this Agreement that is signed by an authorized representative of each party shall be legally binding and enforceable and the parties shall make every reasonable effort to execute duplicate originals of the Agreement.

_____

_____ _____
(signature)

Social Security # _____

CORPORATION

By:_____

Name:_____

Title:_____

Approved:

_____

By:_____
(signature)

Name:_____
(please print)

Title:_____
(please print)

EQUIPMENT

(Commonly Asked Questions
About Equipment Under Grants)

Section 22

NIH GUIDE, Volume 24, Number 15, April 28, 1995

Commonly Asked Questions About Equipment Under Grants

P.T. 34
Keywords: Grants Administration/Policy+
INSTRUMENTS/INSTRUMENTATION/DEVICE
National Institutes of Health

The National Institutes of Health (NIH) Grants Policy Office and awarding institutes and centers frequently receive questions from research administrators and investigators regarding equipment purchased with Public Health Service (PHS) research grant funds. To assist recipients of PHS research grants, NIH staff have developed the following questions and answers regarding equipment. The information below does not represent new policy or a revision to policy. Rather, it is a summary of current regulations and policies pertaining to grant equipment. The answers provided are based on the assumption that there are no special requirements in the program legislation or regulations or special terms and conditions of award that would supersede the regulations and policies cited below.

Appropriate citations to policy or regulation appear within or following each answer. The HHS regulations on the Administration of Grants appear in the Code of Federal Regulations (CFR) at 45 CFR 74 and 45 CFR 92. Part 74 is applicable to all recipients except those covered by Part 92, which governs awards to state and local governments The regulations at Part 74 were recently revised to implement the revision to OMB Circular A-110, and were published in the Federal Register on August 25, 1994 (Vol. 59, No 164)

The PHS Grants Policy Statement (GPS) was revised effective April 1, 1994, and an addendum was effective February 15, 1995. A single copy of each was mailed to all current PHS grantee organizations, which may photocopy the documents as needed. NIH grantees that did not receive a copy may contact the NIH Division of Research Grants, Office of Grants Information, on 301/594-7248 to request a single copy In addition, the GPS is available on the NIH Gopher The NIH Gopher contains information about NIH, including the NIH Guide for Grants and Contracts, and has text-searching capabilities. It is possible to ~tunnel~ to the NIH Gopher (gopher nih gov) if you have access to a system with Gopher Local computer support should be consulted for additional information or assistance

If you have additional questions that cannot be answered by the sponsored research office at your organization, you should contact the grants management specialist identified on your PHS Notice of Grant Award

WHAT IS THE DEFINITION OF EQUIPMENT? The definition for equipment, as stated in 45 CFR Parts 74 and 92, is an article of tangible nonexpendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit However, consistent with recipient organizational policy, lower limits may be established Grantees may implement the new definition (provided they do so consistently on an organization-wide basis) even though the definition in the cost principles may not yet correspond (45 CFR Part 74 2 and 74.34)

DOES THE $5,000 THRESHOLD (UNDER THE REVISED 45 CFR PART 74) ONLY APPLY

DOES THE $5,000 THRESHOLD (UNDER THE REVISED 45 CFR PART 74) ONLY APPLY TO EQUIPMENT PURCHASED AFTER THE EFFECTIVE DATE OF THE REVISION? No. If grantees elect to implement the revised definition, it should be applied to all grantee equipment. Grantees are not required to track equipment under two different definitions.

DOES EQUIPMENT PURCHASED UNDER A GRANT BELONG TO THE PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR? PHS research grants are made to an organization on behalf of the Principal Investigator (PI) or Program Director. Title to equipment acquired with HHS funds vests in the organization receiving financial assistance directly from an HHS awarding agency to carry out a project or program, subject to certain restrictions described at 45 CFR Part 74.34 (see next question). Whereas in the past, title to equipment, property, and supplies purchased under a research grant to a for-profit organization vested in the Federal Government, the revised HHS regulations now permit for-profit grantees to retain title. (45 CFR Part 74.34)

CAN HHS REQUIRE THE TRANSFER OF EQUIPMENT FROM THE GRANTEE TO ANOTHER PARTY? Yes, HHS has the right to require equipment (including title) purchased with grant funds to be transferred to the Federal Government or to an eligible third party named by the HHS awarding office, under the conditions specified in 45 CFR Part 74.34(h). Although it is seldom necessary to do so, this right may be invoked in cases where a grant is transferring to a new organization and the equipment purchased with grant funds is needed to continue the research at the new grantee organization. (45 CFR Part 74.34; GPS, p. 8-13)

DOES THE GRANTEE ORGANIZATION HAVE AN OBLIGATION TO THE GOVERNMENT FOR EQUIPMENT AFTER A GRANT HAS ENDED? Non-profit institutions of higher education and nonprofit organizations whose primary purpose is the conduct of scientific research (hereinafter referred to as exempt grantees) hold title and are exempted from further obligation to the Federal Government for equipment acquired under a PHS grant for support of basic or applied scientific research (except for the HHS right to require transfer as described above). Nonexempt grantees (hospitals, for-profit organizations, and non-profit organizations whose primary purpose is other than scientific research) hold title and must follow the requirements described in 45 CFR Part 74.34 and the PHS Grants Policy Statement, pp 8-10 through 8-14

WHEN IS PHS PRIOR APPROVAL REQUIRED TO PURCHASE EQUIPMENT? Prior approval for the purchase of equipment is required if it will represent a change of scope for the project If the purchase will require significant rebudgeting (see GPS p 8-1), the grantee organization is required to consult with the grants management office for a decision as to whether the rebudgeting constitutes a change of scope In addition, the purchase of equipment exceeding $25,000 (per unit), when not included in the originally approved budget, requires prior approval from PHS, unless the grant was awarded under the Federal Demonstration Project or Expanded Authority terms and conditions (GPS, p. 8-4) (Note equipment costing in excess of $25,000 requires prior approval regardless of the amount of PHS funds to be applied toward the purchase, e g , even if only $5,000 of grants funds will be used toward the purchase of equipment costing $25,001)

IS PHS PRIOR APPROVAL REQUIRED IN ORDER TO REBUDGET FUNDS FOR THE PURCHASE OF GENERAL PURPOSE EQUIPMENT? PHS no longer differentiates between general purpose and special purpose equipment. Thus, other than as described above for equipment in excess of $25,000 or a change of scope, PHS prior approval is not required. However, the expenditure must be reasonable and necessary for the conduct of the grant activities, as well as allowable and allocable as a direct cost to the grant

IS PHS PRIOR APPROVAL REQUIRED TO PURCHASE EQUIPMENT IN THE FINAL SIX MONTHS OF THE PROJECT PERIOD? No. PHS eliminated this prior approval requirement with

MONTHS OF THE PROJECT PERIOD? No. PHS eliminated this prior approval requirement with the revised PHS Grants Policy Statement effective October 1, 1990. Nonetheless, all charges to a grant project, particularly in the final months of the project period, must be allowable and allocable as a direct cost to the grant, and be reasonable and necessary for the conduct of grant activities. Equipment may not be purchased simply to use an unobligated balance remaining at the end of the project.

WHAT HAPPENS TO EQUIPMENT WHEN THE PI MOVES TO ANOTHER ORGANIZATION? The grantee organization is the legal entity to which a grant is awarded. When the PI moves to another organization, the following options apply in the order listed. (45 CFR Part 74.34 and GPS, p. 8- 13)

(1) The grantee organization may request continuation of the project under the direction of an alternate PI. If the alternate PI is approved by PHS, the grant will continue and thus title to the equipment purchased under the grant will remain with the original grantee organization.

(2) The organization may relinquish its interests and rights in the grant to the PI's new organization. If the new organization is approved by the PHS awarding component to continue the grant activity, then the grant will be awarded and any equipment purchased with grant funds and still needed for the grant project would be expected to transfer to the new grantee organization, which would assume title. If the original grantee does not voluntarily agree to relinquish equipment with the grant, HHS may require transfer of the equipment as specified in 45 CFR Part 74.34(h).

(3) If an alternate PI is not accepted by the PHS awarding component (or no alternate is nominated), and the original grantee refuses to relinquish its rights in the grant to the new organization (or if the new organization is not accepted by the PHS awarding component to continue the research), then the grant will be terminated. Title to equipment will remain with the original grantee organization, subject to disposition or use as described below The PI's new organization may submit a new application through the regular NIH peer review process to request support for the research

It is important to reiterate that a change of grantee may not take place where it will involve the transfer of a grant to or between foreign institutions or international organizations (GPS, p. 8-3)

WHAT EQUIPMENT MAY BE CHARGED AS AN ALTERATION AND RENOVATION (A&R) EXPENSE? Fixed equipment, such as casework, a fume hood, a large autoclave, or biological safety cabinet, is an allowable A&R charge Furnishings and movable equipment are not allowable as A&R costs Additional information on alteration and renovation costs can be found in the PHS Grants Policy Statement on pp 7-2 and 7-3

UNDER CONFERENCE GRANTS (R13 OR U13), MAY GRANT FUNDS BE USED FOR THE RENTAL OF EQUIPMENT? Grant funds may be used for the rental of necessary equipment under a conference grant Funds may not be used for the purchase of equipment (GPS, p A7-2)

MAY GRANTEES USE EQUIPMENT ACQUIRED WITH HHS FUNDS TO PROVIDE SERVICES TO NON-FEDERAL ORGANIZATIONS? Yes. However, nonexempt grantees are specifically prohibited from doing so for a fee that is less than private companies charge for equivalent services, unless specifically authorized by Federal statute, for so long as the Federal Government retains an interest in the equipment For both exempt and nonexempt grantees, user charges will accrue as program income and must be reported on the Financial Status Report (SF 269) (45 CFR Part 74 34(b)(1) and 74 24)

ARE DEPRECIATION OR USE CHARGES ON EQUIPMENT AN ALLOWABLE COST ON A GRANT? Depreciation or use charges on equipment are an allowable cost, but not normally allocable as a direct cost to a grant. Such charges are usually included in the organization's indirect cost base for determination of its indirect cost rate. Depreciation or use charges on equipment acquired under a federally supported project are unallowable. (GPS, p. 7-6)

ARE COSTS OF INSURING EQUIPMENT PURCHASED WITH PROJECT FUNDS AN ALLOWABLE EXPENSE? Normally these costs are included in the organization's indirect cost base, but may be allocable as a direct cost if this manner of charging is the normal organizational policy, consistently applied regardless of the source of funds. (GPS, p. 7- 8)

WHAT SHOULD A GRANTEE DO IF A PIECE OF EQUIPMENT IS LOST, DAMAGED, OR STOLEN? The grantee is responsible for maintaining an internal control system to insure adequate safeguards to prevent loss, damage, or theft of equipment purchased with PHS grant funds. If such a system does not exist or is lacking in any way, the grantee must implement any necessary corrective actions.

For non-exempt grantees, if damage, loss, or theft occurs despite the fact that the recipient has the required control system in place, there will be no obligation to PHS for the equipment, unless the recipient receives compensation for the damage, loss, or theft from insurance or some other source. If the grantee is compensated for the damage, loss, or theft, but does not replace the equipment for use on the grant, the rules regarding sale of equipment apply (45 CFR Part 74.34(g)).

HOW MAY EQUIPMENT BE USED AFTER THE END OF A GRANT? Exempt grantees hold title and are exempted from further obligation to the Federal Government for equipment acquired under a PHS grant for support of basic or applied scientific research, except for the HHS right to require transfer as described above.

Nonexempt grantees hold title and shall use the equipment in the project or program for which it was acquired as long as needed, whether or not the project or program continues to be supported by Federal funds, and shall not encumber the property without approval of the HHS awarding agency When no longer needed for the original project or program, the recipient shall use the equipment in connection with its other federally sponsored activities, if any, in the following order of priority:

(1) Program, projects or activities sponsored by the HHS awarding agency; (2) Program projects or activities sponsored by other HHS awarding agencies, (3) Program, projects or activities sponsored by other Federal agencies

If the grantee no longer needs the equipment for the above purposes, the grantee may retain the equipment for other uses, provided that compensation is made to the original HHS awarding agency or its successor If the recipient has no further need for the equipment, it shall request disposition instructions from the HHS awarding agency See 45 CFR Part 74.34(g) for additional information

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Financial Status Report
Standard Form 269A
Blank Form with Instructions

Note: *For foreign grants, this form must be submitted for each budget period funded.*

The Financial Status Report should be submitted with-in 90 days after the end of each budget period to the following address:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
31 Center Drive, Room B1B05A
Bethesda, MD 20892-2052

FINANCIAL STATUS REPORT

(Short Form)

(Follow instructions on the back)

1. Federal Agency and Organizational Element to Which Report is Submitted	2. Federal Grant or Other Identifying Number Assigned By Federal Agency	OMB Approval No. **0348-0038**	Page of pages

3. Recipient Organization (Name and complete address, including ZIP code)

4. Employer Identification Number	5. Recipient Account Number or Identifying Number	6. Final Report ☐ **Yes** ☐ **No**	7. Basis ☐ **Cash** ☐ **Accrual**

8. Funding/Grant Period *(See instructions)* From: (Month, Day, Year)	To: (Month, Day, Year)	9. Period Covered by this Report From: (Month, Day, Year)	To: (Month, Day, Year)

10. Transactions:	I Previously Reported	II This Period	III Cumulative
a. Total outlays			
b. Recipient share of outlays			
c. Federal share of outlays			
d. Total unliquidated obligations			
e. Recipient share of unliquidated obligations			
f. Federal share of unliquidated obligations			
g. Total Federal share *(Sum of lines c and f)*			
h. Total Federal funds authorized for this funding period			
i. Unobligated balance of Federal funds *(Line h minus line g)*			

11. Indirect Expense	a. Type of Rate *(Place "X" in appropriate box)* ☐ **Provisional** ☐ **Predetermined** ☐ **Final** ☐ **Fixed**			
	b. Rate	c. Base	d. Total Amount	e. Federal Share

12. *Remarks: Attach any explanations deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation.*

13. Certification: **I certify to the best of my knowledge and belief that this report is correct and complete and that all outlays and unliquidated obligations are for the purposes set forth in the award documents.**

Typed or Printed Name and Title	Telephone (Area code, number and extension)
Signature of Authorized Certifying Official	**Date Report Submitted**

FINANCIAL STATUS REPORT

(Short Form)

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

Please type or print legibly. The following general instructions explain how to use the form itself. You may need additional information to complete certain items correctly, or to decide whether a specific item is applicable to this award. Usually, such information will be found in the Federal agency's grant regulations or in the terms and conditions of the award. You may also contact the Federal agency directly.

Item	Entry

1, 2 and 3. Self-explanatory.

4. Enter the Employer Identification Number (EIN) assigned by the U.S. Internal Revenue Service.

5. Space reserved for an account number or other identifying number assigned by the recipient.

6. Check *yes* only if this is the last report for the period shown in item 8.

7. Self-explanatory.

8. Unless you have received other instructions from the awarding agency, enter the beginning and ending dates of the current funding period. If this is a multi-year program, the Federal agency might require cumulative reporting through consecutive funding periods. In that case, enter the beginning and ending dates of the grant period, and in the rest of these instructions, substitute the term "grant period" for "funding period."

9. Self-explanatory.

10. The purpose of columns I, II, and III is to show the effect of this reporting period's transactions on cumulative financial status. The amounts entered in column I will normally be the same as those in column III of the previous report in *the same funding period*. If this is the first or only report of the funding period, leave columns I and II blank. If you need to adjust amounts entered on previous reports, footnote the column I entry on this report and attach an explanation.

10a. Enter total program outlays less any rebates, refunds, or other credits. For reports prepared on a cash basis, outlays are the sum of actual cash disbursements for direct costs for goods and services, the amount of indirect expense charged, the value of in-kind contributions applied, and the amount of cash advances and payments made to subrecipients. For reports prepared on an accrual basis, outlays are the sum of actual cash disbursements for direct charges for goods and services, the amount of indirect expense incurred, the value of in-kind contributions applied, and the net increase or decrease in the amounts owed by the recipient for goods and other property received, for services performed by employees, contractors, subgrantees and other payees, and other amounts becoming owed under programs for which no current services or performances are required, such as annuities, insurance claims, and other benefit payments.

10b. Self-explanatory.

10c. Self-explanatory.

10d. Enter the total amount of unliquidated obligations, including unliquidated obligations to subgrantees and contractors.

Unliquidated obligations on a cash basis are obligations incurred, but not yet paid. On an accrual basis, they are obligations incurred, but for which an outlay has not yet been recorded.

Do not include any amounts on line 10d that have been included on lines 10a, b, or c.

On the final report, line 10d must be zero.

10e. f, g, h, h and i. Self-explanatory.

11a. Self-explanatory.

11b. Enter the indirect cost rate in effect during the reporting period.

11c. Enter the amount of the base against which the rate was applied.

11d. Enter the total amount of indirect costs charged during the report period.

11e. Enter the Federal share of the amount in 11d.

Note: If more than one rate was in effect during the period shown in item 8, attach a schedule showing the bases against which the different rates were applied, the respective rates, the calendar periods they were in effect, amounts of indirect expense charged to the project, and the Federal share of indirect expense charged to the project to date.

*U S. Government Printing Office: 1993 - 342-197/81289

SAMPLE CHART OF ACCOUNTS FOR AN ACCOUNTING SYSTEM TO HELP CATEGORIZE CHARGES TO A GRANT

Sample Chart of Accounts

Account Category	Account Code	Account Title
Current Assets		
	1000	Cash
	1020	Accounts Receivable
	1040	Inventory – Work in Progress
	1060	Prepayments
Property, Plant & Equipment		
	1100	Equipment – Lab
	1101	Accumulated Depreciation – Lab Equipment
	1110	Equipment – Office
	1111	Accumulated Depreciation – Office Equipment
	1200	Leasehold Improvements
	1201	Accumulated Amortization – Leasehold Improvements
Other Assets		
	1800	Deposits
Current Liabilities		
	2000	Current Notes Payable
	2010	Accounts Payable
	2030	Accrued Wages and Payroll Taxes Withheld
Long Term Liabilities		
	2100	Notes Payable
Equity		
	3000	Common Stock
	3001	Retained Earnings
Revenue		
	4000	Commercial Sales
	4010	Grant Revenue
	4020	Interest Income
Direct Program Costs		
	5000	Direct Labor
	5100	Consultants
	5200	Equipment
	5300	Materials and Supplies
	5400	Travel
	5500	Other/Miscellaneous
	5600	Consortium/Contractual
Fringe Benefit Costs		
	6010	Vacation
	6015	Holidays
	6020	Sick Leave
	6025	Payroll Taxes
	6030	401(k) Plan
	6035	Group Insurance

Overhead Costs

7000	Overhead Labor
7110	Amortization - Leasehold Improvements
7120	Depreciation - Lab Equipment
7130	Depreciation - Office Equipment
7140	Rent
7150	Utilities
7160	Telephone
7170	Equipment Rental
7180	Expendable Equipment
7190	Repairs & Maintenance
7200	General Lab Supplies
7210	Travel
7220	Consultants
7230	Waste Disposal
7240	Training

General & Administrative (G&A) Costs

8000	G&A Labor
8010	Amortization - Leasehold Improvements
8015	Depreciation - Office Equipment
8020	Rent
8030	Utilities
8040	Telephone
8050	Equipment Rental
8060	Expendable Equipment
8070	Repairs & Maintenance
8080	Office Supplies
8090	Travel
8100	Consultants
8110	Legal & Accounting
8120	Liability Insurance
8130	Licenses
8140	Dues & Subscriptions
8150	Postage
8160	Recruitment/Relocation
8800	IR&D Labor

Unallowable Costs

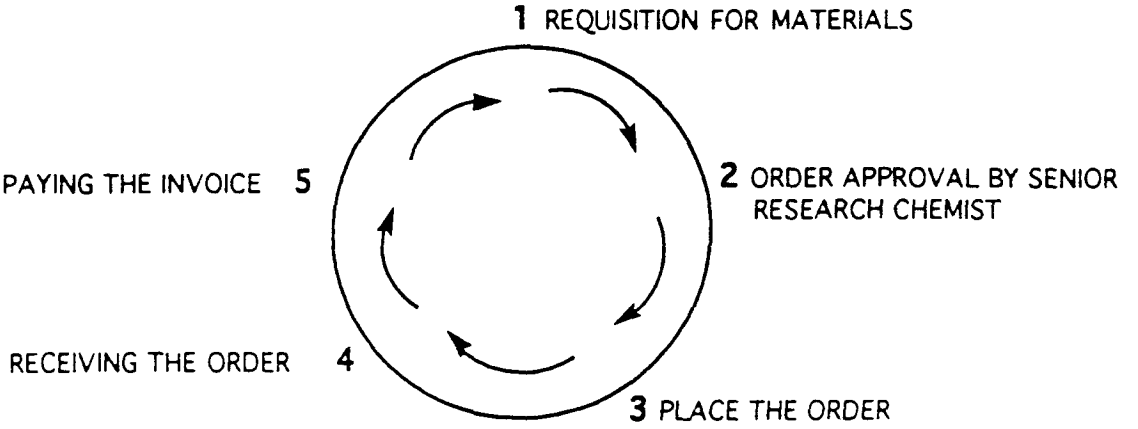
9000	Interest Expense
9010	Contributions
9015	Exhibits

SAMPLE ACCOUNTS PAYABLE FLOWCHART FOR ACCOUNTING PURPOSES

Section 25

ACCOUNTS PAYABLE FLOW

CHECK PROCESSING CIRCLE



1. **Requisition for order**
   (Order is placed using prenumbered purchase order (P.O.))
   * Identify the following on each P.O.

   A Vendor
   B Ship to (receiver)
   C To be billed (if different from ship to)
   D Date ordered
   E Project code
   F Items ordered
   G Description
   H Price (if available)

2. **Order approval by senior research chemist**
   * Key items to look for on approval

   Items A-H (From #1)

3. **Place the order**

   A **Mail**
   Send the approved original (white copy) to the Vendor

   B FAX
   1. Separate the approved original (white copy) from the P.O.
   2. Stamp with faxed stamp and/or attach the fax conformation to the P.O.

   C Phone
   1. Separate the approved original (white copy) from the P.O.
   2. Stamp with phone order stamp (the individual placing the order must initial the P.O.)

   * It is important to obtain the name of the individual who is taking the order over the phone.

4. Receiving the order

A The receiving person must verify:

1. The quantity received with the packing slip
2. The packing slip must be initialed by the individual who verifies the quantity received
3. Attach the packing slip to the receiving copy (pink copy) and forward to accounting for payment

5. Paying to invoice

A The packing slip must be verified with the receiving copy and the invoice:

1. All items listed on the invoice are received
   - 1.a Approve for payment and process check
   - 1.b Attach receivimg report to the invoice and check

2. Items not included/ backorder
   - 2.a Contact Vendor for explanation regarding incomplete order
   - 2.b Note items received on receiving copy
   - 2.c Copy noted receiving copy and approve for payment items received only
   - 2.d Attach the copy/ original receiving report to the invoice and check

6. How is this filed

Original (white copy)
Sent to Vendor or attached to the back of the receiving report

Office copy (yellow copy)
Given to office for maintenance
*input

Receiving copy (pink copy)
Pending file for delivery
*Upon delivery and verification attach receiving documentation and forward to accounting

COMPLETE NIH GRANTS POLICY STATEMENT

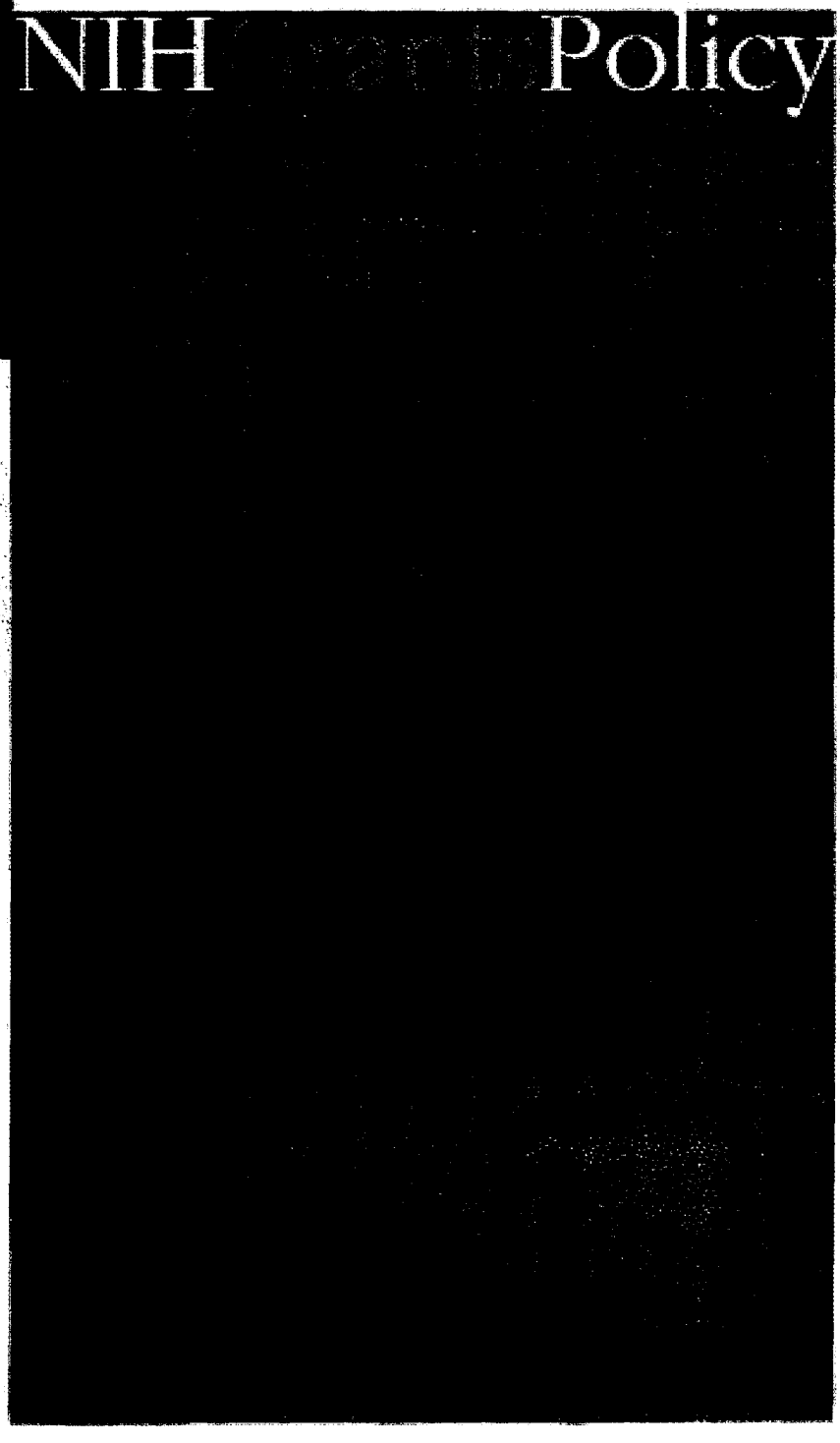
(Revised 03/01)

Section 26

NIH GRANTS POLICY STATEMENT (REV. 03/01)

NIH Grants Policy Statement

(Rev. 03/01)



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

March, 2001

NIH Grants Policy Statement

INTRODUCTION

The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH grantees, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. This document also is designed to be useful to those interested in NIH grants by providing information about NIH—its organization, its staff, and its grants process. The NIHGPS is available on-line from the NIH Home Page at http://www.nih.gov (access the link to "Grants and Funding Opportunities," click on the "Grants Page," and then click on "Grants Policy").

To accomplish these objectives, the document is set up in three 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 grant awards as well as terms and conditions that apply to particular types of grants/grantees/activities that differ from or supplement the standard terms and conditions; and the third 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 terms and conditions that are incorporated by reference in all NIH grant awards. This Part includes generally applicable requirements, which may be in the form of full text or reference to or highlighting of statutory, regulatory, or Office of Management and Budget (OMB) requirements. It also 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; modular grants; and research patient care activities.

Part III

Part III contains general contact information 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. A reference to "Part II" or "Part III" without further elaboration means the corresponding part of this policy statement

SUPERSESSION

The NIHGPS was originally published with an effective date of October 1, 1998 for all NIH grants and cooperative agreements (hereafter, "grants") for budget periods beginning on or after that date. This version of the NIHGPS is an update of the 1998 publication.

This revision of the NIHGPS is effective for all NIH grants and cooperative agreements for budget periods beginning on or after March 1, 2001, and supersedes the October 1998 NIHGPS in its entirety. It remains largely unchanged; however, it incorporates several new and modified requirements, clarifies certain policies, and emphasizes policies that require increased attention by grantees on the basis of recent developments. Among the changes are those that have been published since October 1998 as notices in the *NIH Guide for Grants and Contracts* (NIH Guide). An explanation of the major changes from the NIHGPS that has been in effect since October 1, 1998 is included in the NIH Guide notice announcing the re-issuance of the NIHGPS. The NIH Guide is published on the NIH Home Page at http://www.nih.gov (access the link to "Grants and Funding Opportunities," then click on the "NIH Guide for Grants and Contracts").

MAINTENANCE

The Office of Policy for Extramural Research Administration (OPERA) is responsible for developing and maintaining this document. 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.

Table Of Contents

Part I: NIH Grants—General Information

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 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 Organizational Official: The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards.

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 intervals of time (usually 12 months each) 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 a competing continuation award 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.

Consultant: An individual that provides professional advice or services on the basis of a written agreement for a fee. These individuals are not normally employees of the organization receiving the services. Consultants also include firms that provide professional advice 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.

Co-Investigator: An individual involved with the principal investigator in the scientific development or execution of a project. The co-investigator may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the principal investigator's roles and responsibilities as specified in this policy statement.

Cost Sharing: See "Matching or Cost Sharing."

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

Domestic Organization: A public or private non-profit institution (including Federal, State, and other agencies) or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.

Equipment: An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds the lesser of the capitalization 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.

Fee: An amount in addition to actual, allowable costs incurred that is normally paid to a for-profit organization under a contractual arrangement. This increment above cost also is referred to as "profit." (Also see "Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowability of Costs and Fee—Profit or Fee.")

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

Foreign Component: Under a grant to a domestic organization, 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 organization, with or without grant funds.

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 also are referred to as "commercial organizations."

Full-Time Appointment: The number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH Institute or Center 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 permit 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.

Hospital: A non-profit or for-profit hospital or medical care provider component of a non-profit organization (for example, a foundation). The term includes all types of medical, psychiatric and dental facilities, such as clinics, infirmaries, and sanatoria.

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 terms "NIH IC" or "awarding office" are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award. In the latter case, the terms refer specifically to the designated Grants Management Officer.**

Institutional Base Salary: The annual compensation paid by an applicant/grantee organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

International Organization: An organization that identifies itself as international or intergovernmental, and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.

Key Personnel: 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 and collaborators are 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.

Modular Application: A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

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.

New Investigator: An individual that has not previously served as a principal investigator on any Public Health Service-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory development grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research careers ((K01, K08, and K12). Current or past recipients of Independent Scientist and other non-mentored career awards (K02 and K04) are not considered "new investigators."

Notice of Grant Award: The legally binding document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.

Organization: A generic term used to refer to an educational institution or other entity, including an individual, which 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 designated 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 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."

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Significant Rebudgeting: A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.

Small Business Concern: A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the 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 generally are 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 pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

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 post-award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Total Project Costs: The total allowable costs (both direct costs and 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
OHRP	Office for Human Research Protections
OIG	Office of the Inspector General
OLAW	Office of Laboratory Animal Welfare
OMB	Office of Management and Budget
OPERA	Office of Policy for Extramural Research Administration
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, non-profit 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 are listed in Part III. 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.

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[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 Healthcare Research and Quality (AHRQ), 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.

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 also does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for grantee organizations. The grantee's roles and responsibilities 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 Human Research Protections (OHRP), 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 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 responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The Program Official's responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with CSR/IC Scientific Review Administrators; and postaward administration, including review of progress reports, participating in site visits, and other activities complementary to those of the 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 who 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 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 Allocation office or the Office of Acquisition Management and Policy, NIH[3]; the Division of Payment Management; the Office of the Inspector General; OHRP; the Office of Laboratory Animal Welfare, (OLAW); 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 III includes a list of these organizations and their addresses and telephone numbers.

Grantee Staff

Authorized Organizational 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. In signing a grant application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the grant application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the grant-supported project or activities resulting from the application. (Also see "Legal Implication of Application.") This individual also is responsible to NIH for ensuring that the organization complies with applicable Federal laws and regulations, its application, and the terms and conditions of individual awards. 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) (also may 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 for day-to-day management of the project or program. The PI is not required to be an employee of the grantee. However, since the grant, if awarded, is made to the organization, the applicant organization must have a formal written agreement with the PI that specifies an official relationship between the parties, but need not involve a salary or other form of remuneration. If the PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant, if awarded.

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

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, Intellectual Property Rights, and Sharing Biomedical 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 and the designated GMO concerning the business and administrative aspects of the award.

NOTE: NIH staff conduct official business only with the designated PI and authorized organizational officials.

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 also significant for purposes of applying Part II of this policy statement.

Eligibility

In general, NIH grants may be awarded to organizations that are domestic or foreign, public or private, or non-profit or for-profit. Eligible organizations include governments, 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 II 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 con-

tinuation application," all of the application types listed here 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 (including fellowships) are for investigator-initiated research and are considered "unsolicited" applications. NIH reviews such applications in three review cycles per year.[4] 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 III 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 supplemental, or revised (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 III). CSR will accept such applications for review only if an IC has agreed to accept the application for consideration and the applicant submits with its application a letter to that effect with the name of the authorizing IC official (see "The Peer Review Process"). **An application subject to this policy that does not include the required in-**

[4] Some ICs review applications for Institutional National Research Service Awards (T32s) only once per year. See Appendix II-1 in Part II of this policy statement.

formation 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) 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 common receipt date(s), compete for funding with all other unsolicited applications, and are subject to the standard peer review process. PAs also are 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 awardees as well as joint responsibilities and obligations.

Application Submission

To be considered for support, an applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates. Information to be submitted typically includes a project description, budget and budget justification, biographical sketches of key personnel, and other information specified in the application 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 also must demonstrate compliance (or intent to comply), through certification or other means, with a number of public policy require-

ments. 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 I-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 also are available from Division of Extramural Outreach and Information Resources, Office of Extramural Research, NIH by telephone at (301) 435-0714, by e-mail at GrantsInfo@nih.gov, or by mail at the address listed in Part III. Certain forms (rather than a complete application kit) are available electronically on the NIH Home Page (http://grants.nih.gov/grants/forms.htm).

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://www.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 I-1 REQUIRED FORMS FOR COMPLETING 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 non-construction (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.[5] The address for that office is:

Center for Scientific Review
National Institutes of Health
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.

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

An unsolicited application will be considered to be on time for a particular review cycle if it is received by or mailed on or before the published receipt date for that cycle and a proof of mailing is provided. If the receipt date falls on a weekend or a 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. Only CSR has the authority to waive an established receipt date.

Legal Implication of Application

The signature of an authorized organizational official on the application certifies that the organization will comply with all applicable assurances and certifications referenced in the application. The applicant organization is responsible for verifying the accuracy, validity, and conformity with the most current organizational guidelines of all the administrative, fiscal, and scientific information in the application, including the facilities and administrative cost (indirect cost) rate. The authorized organizational official's signature further certifies that the applicant organization will be accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application.

Applicants for and recipients of NIH grant funds, whether such funds are received directly from NIH, indirectly under a contract or consortium agreement, or as student assistance under a train-

[5] At the present time, NIH is developing and piloting alternative means of electronic submission of applications.

ing 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 also is expected to be in compliance with applicable State and local laws and ordinances.

The HHS OIG maintains a post office box and a toll-free 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 of the OIG and the OIG Hot Line are included in Part III. Anyone who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to NIH grants or grant funds is encouraged to report this information to the OIG in writing or to the OIG Hot Line. Examples of fraud, waste, and abuse that should be reported include, but are not limited to, embezzlement, misuse, or theft of grant funds or property, or making false statements, whether by organizations or individuals. This includes theft of grant funds for personal use; use of funds for non-grant-related purposes; theft of Government-owned property or property acquired or leased under a grant; charging the Government for the services of "ghost" individuals; charging of inflated building rental fees for a building owned by the grantee; submission of false financial reports; and submission of false financial data in bids submitted to the grantee (for eventual payment under the grant).

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

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

Confidentiality of Information (Proprietary Information)

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets or information that is commercial or financial, or information that is privileged or confidential, the pages containing that information should be identified as specified in the instructions provided in the PHS-398 application kit.

When such information is included in the application, it is furnished to the Government in confidence, with the understanding that the information will be used or disclosed only for evaluation of the application. The information contained in an application will be protected by NIH from unauthorized disclosure, consistent with the need for peer review of the application and the requirements of the 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://www.nih.gov/grants/peer/peer.htm. Information also is available by e-mail at DDER@nih.gov or GrantsInfo@nih.gov, or by calling, writing, or faxing a request to CSR (see Part III).

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 Enhance-

ment 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.

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

CSR Referral Officers, who are senior health science administrators with both research and scientific review experience, assign each application to 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 multi-year 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.

The 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 organizational 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. These procedures call for limited budget information to be submitted with the application (e.g., a budget justification and a modified biographical sketch) and allow for a possible NIH request for additional information, including information concerning other support, when the application is under consideration for funding. "Just-in-time" procedures also allow an applicant to defer certification of Institutional Review Board (IRB) approval of the project's proposed use of human subjects until after completion of the peer review and just prior to funding. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

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

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 fea-

tures of the scientific environment or employ useful collaborative arrangements? Is there evidence of organizational 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 also will form the basis of the review of solicited applications and non-research activities. However, for some activities (e.g., construction grants), the use of these criteria, as stated, may not be feasible. Applications also may be reviewed against specific criteria as stated in RFAs or PAs.

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

- 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 also will 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.

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 official 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 official, who will handle it in accordance with specific appeal procedures.

The program official 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, non-compliant modular 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 changed or 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 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://www.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 Division of Extramural Outreach and Information Resources (at the address shown in Part III).

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://www.nih.gov/grants/funding/funding.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://www.nih.gov/grants/oer.htm. The NIH Guide also is available on a subscription basis. For subscription instructions, see http://www.nih.gov/grants/guide/listserv.htm.

***Research Grants and Contracts*:** annual listing of extramural awards, previously known as "the brown book." The Web site address is http://www.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 also are accessible by title at http://www.nih.gov/grants/documentindex.htm. IC Home Pages also should be consulted for IC-specific guidelines (see Part III).

Other documents providing information about or general descriptions of NIH programs also may 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 III for current Web site addresses).

Part II: Terms and Conditions of NIH Grant Awards

Subpart A: General

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, review of the project budget, assessment of the applicant's management systems, and determination of applicant eligibility and compliance with public policy requirements. The applicant may be asked to submit additional information or to undertake certain activities (such as negotiation of a facilities and administrative (F&A) cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if special conditions are required, and 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 also has 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 by submitting documentation or by a certification accomplished by the authorized organizational official's signature on the application (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 GMO also will verify whether the applicant, proposed PI, or other key personnel are debarred or suspended from participation in Federal assistance programs (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations" for certification requirements).

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."

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 requires a detailed budget. Cost analysis involves obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining data to determine the necessity for, and the reasonableness and allowability of, the costs included in the application budget. The extent of cost analysis will depend on the type of funding instrument, the complexity of the project, prior experience with the applicant, and other factors. Information on the applicable cost principles and on allowable

and unallowable costs under NIH grants is provided in "Cost Considerations."

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

OVERVIEW OF TERMS AND CONDITIONS

The remainder of Part II serves as the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH awards. Subpart A includes those terms and conditions that apply, in general, to NIH awards, and Subpart B includes additional or alternate terms and conditions for particular types of awards, recipients, or activities.

These terms and conditions are not intended to be all-inclusive. In addition to the requirements 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 also may contain award-specific terms and conditions. For example, the GMO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of 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.

These terms and conditions are intended to be compliant with governing statutes and the requirements of 45 CFR Parts 74 and 92, as modified by previously approved waivers and deviations. However, if there is a perceived conflict between or among these three categories of requirements, i.e., statutory and regulatory requirements, the terms and conditions in 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 designated 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 specified in the NGA.

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, consortium participants, and contractors, in general, or may relate to the expenditure of Federal funds for research or other specified activities. In addition to cross-cutting requirements that 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 in this section set many of those standards. The signature of the authorized organizational official on the application certifies that the organization is in compliance with, or intends to comply with, all applicable certifications and assurances referenced (and, in some cases, included) in the application package. These include the following as discussed in this section:

- Debarment and Suspension (specific certification language included in application package)
- Drug-Free Workplace
- Lobbying (specific certification language included in application package)
- Financial Conflict of Interest
- Research Misconduct and Instruction in the Responsible Conduct of Research
- Delinquent Federal Debt
- Human Pluripotent Stem Cell Research
- Human Subjects
- Research on Transplantation of Fetal Tissue
- Vertebrate Animals
- Inclusion of Women, Children, and Minorities in Clinical Research
- Age Discrimination

- Civil Rights
- Sex Discrimination
- Handicapped Individuals

As noted in this section, some certifications and assurances may require submission of a separate document (e.g., human subjects assurance, Institutional Review Board certification, and civil rights assurance). Applicants and grantees should take particular note of these requirements (for example, see "Human Subjects" and "Civil Rights"), the absence or inadequacy of which may delay an award or make an applicant ineligible for award.

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

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

Table II-1 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 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 designated GMO if there is any question concerning the applicability of a particular public policy requirement or objective.

The listing in Table II-1 indicates where, in this policy statement, the individual public policy requirements and objectives are covered in more detail. However, the governing statute, regulations, or other cited policies or documents should be consulted for complete information.

TABLE II-1
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	Availability of Information 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	Civil Rights National Research Service Awards Awards to Foreign Institutions, International Organizations and Domestic Grants with Foreign Components (hereafter, Awards to Foreign Institutions)
Animal Welfare	X	X	X	Animal Welfare National Research Service Awards Awards to Foreign Institutions
Ban on Human Embryo Research and Cloning	X	X	X	Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients or Recipients of Services (hereafter, Requirements Affecting the Rights and Welfare of Individuals)
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)	Civil Rights National Research Service Awards Awards to Foreign Institutions
Confidentiality of Patient Records	X	X	X	Requirements Affecting the Rights and Welfare of Individuals
Controlled Substances	X	X	X	Requirements Affecting the Rights and Welfare of Individuals
Data and Safety Monitoring	X	X	X	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)	Ethical and Safe Conduct in Science and Organizational Operations Awards to Foreign Institutions
Drug-Free Workplace	X	N/A	N/A	Ethical and Safe Conduct in Science and Organizational Operations Awards to Foreign Institutions

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)	Civil Rights National Research Service Awards Awards to Foreign Institutions
Elimination of Architectural Barriers to the Handicapped	X	N/A	X	Construction Grants
Financial Conflict of Interest	X (N/A to Phase I of the SBIR/STTR programs and to Federal institutions)	X	N/A	Ethical and Safe Conduct in Science and Organizational Operations Grants to Federal Institutions and Payments to (or on behalf of) Federal Employees under Grants
Flood Insurance	X	N/A	NA	Construction Grants
The Freedom of Information Act	X (Applies to certain research data produced by specified types of grantees; N/A to commercial organizations)	X (Applies to certain research data produced by specified types of grantees; N/A to commercial organizations)	X Applies to certain research data produced by specified types of entities; N/A to commercial organizations)	Availability of Information
Health and Safety Guidelines	X	X	Applies as required by Federal, State or local regulations	Ethical and Safe Conduct in Science and Organizational Operations
Historic Properties/ Archeological Sites	X	N/A	X	Construction Grants
Human Pluripotent Stem Cell Research	X	X	X	Ethical and Safe Conduct in Science and Organizational Operations
Human Subjects	X	X	X	Requirements Affecting the Rights and Welfare of Individuals National Research Service Awards Awards to Foreign Institutions
Inclusion of Children as Subjects in Clinical Research	X	X	N/A	Requirements for Inclusiveness in Research Design National Research Service Awards Awards to Foreign Institutions

Requirement or Objective	Grantee	Consortium Participant	Contractor under Grant (Routine Goods/Services)*	GPS Section for Additional Information
Inclusion of Women/Minorities as Subjects in Clinical Research	X	X	N/A	Requirements for Inclusiveness in Research Design National Research Service Awards Awards to Foreign Institutions
Intergovernmental Review under EO 12372	X	N/A	N/A	Construction Grants
Investigational New Drug Applications/ Investigational Device Exceptions	X	X	X	Requirements Affecting the Rights and Welfare of Individuals
Labor Standards under Federally Assisted Construction	X	N/A	X	Construction Grants
Limitation on Use of Funds for Promotion or Legalization of Controlled Substances	X	X	X	Ethical and Safe Conduct in Science and Organizational Operations
Lobbying	X Certification required if total costs expected to exceed $100,000	X Certification required if greater than $100,000 only	X Certification required on contracts greater than $100,000 only	Ethical and Safe Conduct in Science and Organizational Operations
Metric System	X	X	X	Other Public Policy Requirements and Objectives Construction Grants
Military Recruiting and ROTC Program Access to Institutions of Higher Education	X	X	X	Other Public Policy Requirements and Objectives
National Environmental Policy Act of 1969	X	N/A	N/A	Construction Grants
Nondelinquency on Federal Debt	X	X	N/A	Ethical and Safe Conduct in Science and Organizational Operations Awards to Foreign Institutions
The Privacy Act	X Applies to covered material in NIH's possession	X Applies to covered material in NIH's possession	X Applies to covered material in NIH's possession	Availability of Information

Requirement or Objective	Grantee	Consortium Participant	Contractor under Grant (Routine Goods/Services)*	GPS Section for Additional Information
Pro-Children Act of 1994	X	X	X	Requirements Affecting the Rights and Welfare of Individuals
Program Fraud and Civil Remedies and False Claims Acts	X	X	N/A	Application and Review Processes—Legal Implication of Application
Protection of Research Subjects' Identity	X	X	X	Requirements Affecting the Rights and Welfare of Individuals
Public Disclosure	X	N/A	N/A	Construction Grants
Recombinant DNA Molecules	X	X	X	Ethical and Safe Conduct in Science and Organizational Operations 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)	Civil Rights National Research Service Awards Awards to Foreign Institutions
Relocation Assistance and Real Property Acquisition	X	N/A	N/A	Construction Grants
Research Misconduct	X	X	N/A	Ethical and Safe Conduct in Science and Organizational Operations Awards to Foreign Institutions
Research on Transplantation of Fetal Tissue	X	X	X	Requirements Affecting the Rights and Welfare of Individuals
Restriction on Distribution of Sterile Needles	X	X	X	Ethical and Safe Conduct in Science and Organizational Operations
Seat Belt Use	X	N/A	N/A	Ethical and Safe Conduct in Science and Organizational Operations
Smoke-Free Workplace	X	N/A	N/A	Ethical and Safe Conduct in Science and Organizational Operations
Standards of Conduct	X	N/A	N/A	Ethical and Safe Conduct in Science and Organizational Operations

*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 recipient organizations are responsible in their handling of Federal awards. Grantees are required to adopt and enforce policies that minimize the opportunity for improper financial gain on the part of the organization, their employees, and organizations and individuals with whom they may collaborate, and that limit the potential for research results to be tainted by possible personal financial or other gain.

In addition, NIH grantees are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.

Standards of Conduct

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 also must:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper;
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official;
- Include a process for notification and review by the responsible official of potential or actual violations of the standards; 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, to NIH. The grantee is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and informing the IC Chief Grants Management Officer (CGMO) 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 designated GMO must be notified as specified in "Administrative Requirements—Changes in Project and Budget."

Financial Conflict of Interest

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 PHS Funding is Sought." That subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator. These requirements do not apply to 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 the CGMO the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 identified by the organization;
- When informing the CGMO that a financial conflict of interest has been identified, the organization will assure that the interest has been addressed in accordance with the regulations by indicating whether the conflict has either been managed, reduced, or eliminated;
- The organization will continue to make similar reports on subsequently identified conflicts; and
- The organization will make additional information available to NIH, upon request, as to how identified conflicting interests have been handled in accordance with the regulations.

As described in the regulations, examples of how financial conflicts of interest might be addressed include the following:

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

Grantees also must ensure that consortium agreements address whether the consortium participant's employees will be subject to the financial conflict of interest requirements of the collaborating organization or to those of the grantee (see "Consortium Agreements").

The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing, and reporting data. Although there is no regulatory requirement for Institutional Review Boards (IRBs) to consider investigator financial conflict of interest, in some cases IRBs are incorporating conflict of interest issues in their deliberations (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects.")

Some strategies used by IRBs to consider investigator conflict of interest include the following:

- Make IRBs aware of the organization's conflict of interest policies and procedures and elect to include a statement in the informed consent form that all clinical investigators comply with the organizational guidelines.

- Ask investigators to complete a short questionnaire in which they are asked whether they or any person responsible for the design, conduct, or reporting of research have an economic interest in, or acts as an officer or a director of any outside entity whose financial interest could reasonably appear to be affected by, the research.

- Provide instruction to IRB members during their orientation on how to identify and respond to a perceived financial, academic, or other conflict of interest.

Debarment and Suspension

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

- Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

- Have not, within the 3-year period preceding the application, been convicted of, or had a civil judgment rendered against them for, 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;

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

- 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.

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

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

Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the authorized organizational 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.orcbs.msu.edu/biological/BMBL/BMBL-1.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. These regulations are available at http://www.osha.gov/comp-links.html.

- *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; or on-line at http://books.nap.edu/catalog/4911.html (ISBN)-309-05229-7).

- 42 CFR Part 72, *Interstate Shipment of Etiological Agents,* and, in particular, 42 CFR 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 applicable 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

Grantees are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedule of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812. This limitation does not apply if 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").

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, which are not subject to this prohibition.

Applicants for NIH awards with total costs expected to exceed $100,000 are required to certify that (1) they have not made, and will not make, such a prohibited payment, (2) they will be responsible for reporting the use of non-appropriated funds for such purposes, and (3) 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 organizational official on the application serves as the required certification of compliance for the applicant organization. Disclosure reporting is addressed in "Administrative Requirements—Monitoring—Reporting."

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

Research Misconduct

The grantee will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. 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 research misconduct. The signature of the authorized organizational official on the application certifies that the organization has established administrative policies as required by 42 CFR 50, Subpart A, and will comply with those policies and the requirements of the regulations. The regulations are available from the Office of Research Integrity (ORI) on its home page (http://www.ori.dhhs.gov) and, in hard copy, at the address shown in Part III.

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 research misconduct has been found or where a research misconduct inves-

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

If a misconduct investigation has been initiated, the grantee must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project(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 research misconduct 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 research misconduct.

The grantee is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. When a finding of research misconduct has been made regarding conduct by an individual(s) working on an NIH grant-supported project, whether at the grantee organization or at a third-party organization, the grantee must assess the effect of that finding on the ability to continue that project, as originally approved by NIH, and must promptly obtain NIH approval of any intended change of PI or other key personnel. A finding of research misconduct 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."

Where the validity or reliability of data has been affected by research misconduct, 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. ORI or NIH may require corrections or retractions. 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 III).

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. NIH cannot award a grant unless the authorized organizational official of the applicant organization (or individual in the case of an Individual National Research Service Award) certifies, by means of his/her signature on the application, that the organization is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal Government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the

debt is repaid or satisfactory arrangements made, NIH will 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 Molecules

Scope and Applicability

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (the NIH Guidelines) (65 FR 60328, October 10, 2000 or latest revision) apply to all NIH-funded and non-NIH funded gene transfer projects that are conducted at or sponsored by an organization that receives NIH support for recombinant DNA research. A copy of the NIH Guidelines is available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html. As defined by the NIH Guidelines, recombinant DNA molecules are either (1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) DNA molecules that result from the replication of those described in (1). The NIH Guidelines apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the NIH Guidelines. Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funds for recombinant DNA research at the organization or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization. Two specific requirements of the NIH Guidelines are discussed below, but the NIH Guidelines should be carefully reviewed, in their entirety, to ensure compliance with all of the requirements for the conduct of projects involving recombinant DNA techniques.

Institutional Biosafety Committee

Each organization that conducts research involving recombinant DNA, including contractors under grants, must have policies and procedures to ensure compliance with the NIH Guidelines and must establish a standing Institutional Biosafety Committee (IBC). The IBC is required to review each proposed project for recombinant DNA experiments and certify that the procedures, project, personnel, and facilities are adequate and in compliance with the NIH Guidelines. The composition requirements of IBCs are specified in section IV of the Guidelines. A roster of the members of the IBC must be submitted to the Office Biotechnology Activities (OBA), NIH (see Part III for address). At a minimum, the roster should include the names, addresses, occupations, and qualifications of the chairperson and members of the committee. Section IV of the NIH Guidelines specifies the roles and responsibilities of PIs and grantees in relation to IBCs and in other areas.

Serious Adverse Event Reporting

The NIH Guidelines currently require the immediate reporting of serious adverse events that occur in human gene transfer clinical studies. As specified in Appendix M-I-C-4, investigators that have received authorization from the Food and Drug Administration (FDA) to initiate a human gene transfer research protocol must report any serious adverse event immediately to the local IRB (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects—Assurance Requirements and Institutional Review Boards"), the IBC, the Office for Human Research Protections (OHRP) (if applicable), and OBA (at the address specified in Part III of this policy statement), followed by the filing of a written report with each office/group[7]. The Guidelines, available from OBA, should be consulted for complete requirements for the conduct of projects involving recombinant DNA techniques.

Human Pluripotent Stem Cell Research

NIH will fund research using human pluripotent stem cells derived from human embryos (technically known as human embryonic stem cells) or human fetal tissue (technically known as human embryonic germ cells). NIH published final *NIH Guidelines for Research Using Human Pluripotent Stem Cells* (Guidelines) that were effective on August 25, 2000. Because the Guidelines contained a few incorrect citations and other minor errors, they were corrected on November 21, 2000 (http://www.nih.gov/news/stemcell/stemcellguidelines.htm). The Guidelines establish procedures to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner. Such research also is subject to the informed consent requirements of section 498A of the PHS Act.

NIH Guidelines for Research Using Human Pluripotent Stem Cells

For purposes of the Guidelines, human pluripotent stem cells are cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not in themselves embryos. NIH research funded under these Guidelines will involve human pluripotent stem cells derived: (1) from human fetal tissue, or (2) from human embryos that are the result of *in vitro* fertilization, are in excess of clinical need, and have not reached the stage at which the mesoderm is formed. NIH funds may not be used to derive human pluripotent stem cells from human embryos. The Guidelines designate certain areas of human pluripotent stem cell research as ineligible for NIH funding.

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[7] The scope and timing of this and other safety reporting requirements is under review. The OBA Home Page (http://www4.od.nih.gov/oba/) should be consulted for developments that may affect the timing of submission of safety reports.

Human Pluripotent Stem Cell Review Group

The approval process for NIH research proposed for support under grants and cooperative agreements is described at http://www.nih.gov/news/stemcell/NOT-OD-00-050.html. In addition to the peer review process described in Part I of this policy statement, research that proposes to use human pluripotent stem cells will undergo a formal review of documentation of compliance with the Guidelines. This latter review will be conducted by the Human Pluripotent Stem Cell Review Group (HPSCRG), which is a working group of the Center for Scientific Review Advisory Council (CSRAC). The process for documenting compliance with the Guidelines is separate from the grant and cooperative agreement scientific review process. The two processes will take place in parallel in order to ensure that all aspects of scientific review and review of compliance are considered in a timely manner. Organizations and investigators proposing research using human pluripotent stem cells must be mindful of the requirements and deadlines for both processes in order to avoid delays in the potential funding of proposed research. NIH will not provide funds or allow existing funds to be used for research involving human pluripotent stem cells derived from human embryos or human fetal tissue until appropriate approvals have been obtained. Evidence of compliance with the Guidelines does not affect the peer review of the application nor does it ensure a favorable funding decision by NIH. The documentation requirements and approval process also apply to requests to conduct research using human pluripotent stem cells that are not part of a competitive process, i.e., that are part of an administrative supplemental request or a prior approval request for a change in scope.

When the HPSCRG receives compliance documentation in support of a request that proposes use of a the line of human pluripotent stem cells that has not been previously reviewed by the HPSCRG and recommended to, and approved by, the CSRAC, the HPSCRG review will take place in a public meeting. Thus, although the HPSCRG will review all requests for funds, the review of compliance documentation for the use of a cell line previously approved by NIH will not take place in a public meeting of the HPSCRG. The final approval of documentation of compliance always will take place in a public meeting of the CSRAC. Meetings of the CSRAC are open to the public. Following meetings of the CSRAC, the NIH Office of Science Policy will convey the results of the human pluripotent stem cell compliance review to the principal investigator, the organization, and the potential funding IC.

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 (1) exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, and (2) 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 subsection 498 (a) and (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 subsections 498 (a) and (b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

Research on Human Fetal Tissue

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definitions does not include established human fetal cell lines.

NIH Guidance for Research on Human Fetal Tissue

NIH has issued guidance for grantees conducting research on human fetal tissue. The guidance and other information on the governing federal statute, Sections 498A and 498B of the Public Health Service Act, 42 USC 289g-1 and 298g-2, are available on the NIH web site at http://grants.nih.gov/grants/guide/notice-files/not93-235.html
The scientific and ethical challenges associated with research utilizing human fetal tissues make it imperative that researchers and their institutions be clearly aware of and in compliance with the federal requirements particularly section 498B. Violation of this statute carries criminal penalties that are applicable to both the suppliers and the acquirers of human fetal tissue for valuable consideration.

When an application involving human fetal tissue research is submitted to the NIH, the authorized institutional official certifies (by signing the face page) that researchers using these tissues are in compliance with Sec 498B of the Public Health Service Act, 42 U.S.C. 289g-2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to

profit, and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control or transportation of these tissues.

There are additional legal requirements for research on the transplantation of human fetal tissue for therapeutic purposes that is conducted or supported by the NIH. (See Sec 498A and Sec 498B(b) of the Public Health Service Act.) Under section 498A the institutional official who signs the application must certify that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the tissue is being donated for therapeutic transplantation research, that the donation is being made without any restriction regarding the identity of individuals who may receive the transplantation, and that the donation is being made without the donor knowing the identity of the recipient.

- The attending physician must sign a statement that the tissue has been obtained in accordance with the donor's signed statement and that full disclosure has been provided to the donor with regard to the physician's intent, if any, in the research to be conducted with the tissue, and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks of the type that are associated with the woman's medical care. In the case of tissue obtained pursuant to an induced abortion, the physician's statement must also state that the woman's consent for the abortion was obtained prior to requesting or obtaining consent for the tissue to be used; no alterations of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue for research; and the abortion was performed in accordance with applicable State and local law.

- The principal investigator must sign a statement certifying that he or she is aware that the tissue is human fetal tissue obtained pursuant to a spontaneous or induced abortion, or pursuant to a stillbirth, that is being donated for research purposes. The principal investigator must also certify that: this information has been shared with others who have responsibilities regarding the research; and prior to eliciting informed consent from the transplantation recipient, the researcher will obtain written acknowledgement that the patient is aware of the aforementioned information. Moreover, the principal investigator will certify in writing that he or she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy that were made solely for the purposes of the research.

- Research involving the transplantation of human fetal tissue must be conducted in accord with applicable State and local law.

The institutional official must certify that the physician's statement, statement of the researcher, and the acknowledgement of the transplantation recipient will be available for audit by the Secretary, DHHS, or designee.

Confidentiality

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

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.

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 also is 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. Under the governing regulations, a grantee may not conduct research involving human subjects or expend Federal funds for research involving human subjects at any site, domestic or foreign, unless it has an Office for Human Research Protections (OHRP)-approved assurance of compliance with the requirements of 45 CFR Part 46 and the research has been approved by an Institutional Review Board (IRB) in accordance with the requirements of 45 CFR Part 46. 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.) OHRP should be consulted if there is any question concerning the classification of research as exempt or nonexempt.

Assurance Requirements and Institutional Review Boards

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 Human Research Protections (OHRP) 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 additional performance sites for the grant-supported research also must file an Assurance. OHRP is responsible for negotiating and approving the Assurance. Previously OHRP (and its predecessor organization—the Office for Protection from Research Risks) negotiated several types of assurances, e.g., a Multiple Project Assurance (MPA) or a Single Project Assurance (SPA) as well as an Inter-Institutional Amendment if employees of an organization with an MPA routinely conducted their grant-supported research at an affiliated institution, thereby avoiding the need for an SPA for each separate project performed at such sites.

OHRP is now negotiating Federalwide Assurances (FWA) covering all of an organization's federally supported research activities involving human subjects. Therefore, for organizations proposing research involving human subjects and not currently holding an approved assurance(s), OHRP will negotiate an FWA. Under the new system, each legally separate entity must file its own FWA even if the organization does not operate its own IRB and designates another IRB (registered with OHRP and agreeing to the designation) for that purpose. Organizations currently operating under SPAs, MPAs and/or other Assurances will continue to operate under the terms of their current assurances, including time of submission of certification of IRB review, until converted to an FWA[8]. Detailed information concerning FWAs, including the OHRP Assurance Training Module, are available on the OHRP web site.

NIH will not award a grant in which human subjects are involved for non-exempt research unless the grantee has an OHRP-approved assurance and the grantee provides a certification to NIH that the research has been approved by an appropriate IRB, consistent with 45 CFR Part 46, within 12 months prior to the budget period start date. IRB approval is not required prior to NIH peer review of an application. Therefore, following peer review and notification of priority score/percentile, applicant organizations should proceed with IRB review for those applications that have not yet received IRB approval and that appear to be in a fundable range. Regardless of when the IRB review occurs, the IRB should ensure that the research described in the application is consistent with any corresponding protocols reviewed and approved by the IRB. It is the grantee organization's responsibility to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved assurance and IRB approval of the research consistent with 45 CFR Part 46, and to comply with NIH prior approval requirements related to the addition of sites not included in the approved application (see "Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements"). The list of organizations with

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[8] After February 28, 2001 OHRP will no longer routinely accept assurances that are limited to HHS-supported research, to special categories of research, or to individual research projects. Current MPAs will remain in effect until the designated expiration date or December 31, 2003, whichever comes first; however, MPA organizations may file a new FWA at any time prior to that date and they are encouraged to do so as soon as possible. MPAs that have been administratively extended by OHRP must be replaced with an FWA no later than March 1, 2001. OHRP will not accept changes to existing MPAs (except for IRB membership updates). If changes are necessary, the organization should file an FWA.

approved assurances is available at the OHRP web site (http://ohrp.osophs.dhhs.gov). **Grantees may not draw funds from the payment system or make obligations against Federal funds for research involving human subjects at any site engaged in non-exempt research for any period not covered by both an OHRP-approved assurance and an IRB approval consistent with 45 CFR Part 46.** 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.

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

The regulations specify additional protections for research involving 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 OHRP.

Information concerning the preparation and negotiation of Assurances, as well as copies of the regulation, may be obtained from OHRP at the address shown in Part III or from its home page at

http://ohrp.osophs.dhhs.gov. OHRP also has produced a publication available through the Government Printing Office[9] and an instructional videotape.

Education in the Protection of Human Research Participants

Before funds are awarded for competing applications involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research. Key personnel include all individuals responsible for the design or conduct of the study. The description of education should be part of a cover letter that accompanies the description of "other support," IRB approval, and other information submitted prior to funding in accordance with "just-in-time" procedures. For non-competing continuations, the description of education should be part of the documentation submitted as a prerequisite to award (whether under the Streamlined Noncompeting Award Process or submitting a full non-competing continuation application).

Data and Safety Monitoring

NIH requires oversight and monitoring of all human intervention studies to ensure the safety of participants and the validity and integrity of the data. This policy is in addition to any monitoring requirements imposed by 45 CFR Part 46 (see "Human Subjects" in this subsection), FDA, or the *NIH Guidelines for Research Involving Recombinant DNA Activities*. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. Oversight and monitoring under Phase III clinical trials should be in the form of Data Safety Monitoring Boards (DSMBs). A DSMB also may be appropriate for Phase I and II clinical trials if the studies have multiple clinical sites, are blinded (masked), or employ particularly high-risk or vulnerable populations. The DSMB monitoring function is above and beyond that traditionally provided by IRBs; however, the IRB must be cognizant of the procedures used by DSMBs, and the DSMBs must provide periodic reports to investigators for transmittal to the local IRB.

For competing research applications involving Phase I or II clinical trials, the applicant must include a general description of the data safety monitoring for review by the Scientific Review Group. A detailed monitoring plan must be included as part of the research protocol, be submitted to the local IRB, and be reviewed and approved by the funding IC prior to initiation of the trial. At a minimum, monitoring plans must include a description of the reporting mechanisms for advising the IRB, FDA, and NIH of adverse events. In specific cases where the funding IC is the sponsor of the test agent, i.e., the holder of the Investigational New Drug Application, investigators must submit individual adverse event reports to the IC in accordance with FDA regulations. If a safety monitoring committee has been established for Phase I or II trial, summary reports of the committee's discussions must be submitted to the IC and to the IRB. The funding IC may specify the reporting requirements for adverse events, which are in addition to annual report to the IRB.

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[9] *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 OHRP's Web site (http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm).

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

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

Further information concerning these requirements is contained in several *NIH Guide for Grants and Contracts* notices (http://grants.nih.gov/grants/guide/notice-files/not98-084.html) and (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html).

Investigational New Drug Applications/Investigational Device Exceptions

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 to be eligible for funding. As provided in the FDA regulations, an IND or Investigational Device Exception (IDE) also may apply to biologics or devices. The FDA regulations are published at 21 CFR Parts 50 and 312.

The official sponsor of the IND/IDE, whether NIH, a grantee, or a third party, is legally responsible for meeting the FDA requirements. If a third party, such as a pharmaceutical company or research organization under contract to a grantee or to a pharmaceutical company, is the IND/IDE sponsor, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the sponsor rather than the grantee. This generally will be the case for larger, multi-site clinical trials. If the grantee is the IND/IDE holder, commonly referred to as an "investigator-initiated IND/IDE," the grantee or the investigator serves as the sponsor and assumes the legal responsibility. In any case, the grantee is ultimately responsible to NIH for ensuring compliance with the requirements for protection of human subjects, including compliance with FDA's requirements.

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

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

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

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

Pro-Children Act of 1994

Public Law 103-227, Title X, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (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 redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the 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.

Research on Transplantation of Fetal Tissue

In submitting an application to NIH, the authorized organizational 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.

Animal Welfare

The *PHS Policy on Humane Care and Use of Laboratory Animals* (the Policy) requires that applicant organizations proposing to use vertebrate animals in NIH-supported activities file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare, 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. It requires the applicant to establish appropriate policies and procedures for humane care and use of animals, based on the *Guide for the Care and Use of Laboratory Animals*, and to comply with the Animal Welfare Act and its implementing regulations. This includes 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 OLAW.

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

Information concerning the preparation and submission of Animal Welfare Assurances as well as copies of the Policy and other relevant materials are available from OLAW (see Part III for contact information). Information concerning ways in which to reduce the administrative burden associated with these requirements also is available at OLAW web site http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-007.html.

Requirements for Inclusiveness in Research Design

NIH requires 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 childbearing 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 a separate policy on inclusion of children as subjects in clinical research that is similar to the policy regarding inclusion of women and minorities. All new applications involving human subjects research 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[10]. If children will be excluded from the research, the application must present an acceptable justification for the exclu-

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[10] This policy has been in effect since October 1, 1998 for new applications submitted for a receipt date after that date. It is not mandatory for applications submitted for receipt dates prior to that date, competing awards made prior to that date, or non-competing awards resulting from competing awards made prior to that date.

sion. 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 certify (by means of the authorized organizational official's signature on the application) that it has an Assurance of Compliance with the statutes described in this subsection on file with the Office for Civil Rights (OCR), Office of the Secretary, HHS. The Assurance, Form HHS-690, is filed on an organizational 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 also is 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 required to file this Assurance, and the applicant/grantee is responsible for determining whether those organizations have the required Assurance on file and, if not, ensuring that it is filed with OCR.

Age Discrimination Act of 1975

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

Civil Rights Act of 1964

Title VI of the Civil Rights Act of 1964 provides that no person in the 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 pro-

gram 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—Public Policy Requirements and Objectives." However, they also may apply to alteration and renovation (A&R) activities. A grantee undertaking an A&R project under a nonconstruction award should consult the GMO concerning potential applicability of these requirements.

Availability of Information

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 in the 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, available from the Office of Extramural Research Home Page. 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 described in this subsection.

Several policies require acknowledgment of support and a disclaimer for publications, inventions, and other research products, as provided in "Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources" and elsewhere in this policy statement. The following disclosure requirement ("Acknowledgment of Federal Funding") is included in HHS appropriations statutes.

Acknowledgment of Federal Funding

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

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 generally do not require grantees or contractors under grants to permit public access to their records. An exception related to certain research data is described in this subsection.

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

- 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.

NIH will generally withhold the following types of records or information 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, a designated NIH or HHS FOIA Officer will delete the nondisclosable information, and the balance of the document will be disclosed.

Access to Research Data

By regulation (45 CFR 74.36), grantees that are institutions of higher education, hospitals, or non-profit organizations are required to release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (e.g., regulations and administrative orders)[11]. "Research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

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

Requests for the release of research data subject to this policy are required to be made to NIH, which will handle them as FOIA requests. If the data are publicly available, the requestor will be directed to the public source. Otherwise, the IC FOIA coordinator, in consultation with the affected grantee and the PI, will handle the request. This policy also provides for assessment of a reasonable fee to cover grantee costs as well as (separately) the NIH costs of responding.

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 informa-

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[11] These requirements apply to data first produced under a competing award (new, competing continuation, or competing supplement) made after April 17, 2000, and any subsequent non-competing award pursuant to those competing awards.

tion 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" 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.

THE NOTICE OF GRANT AWARD

The NGA is the legal document issued to notify the grantee that an award has been made and that funds may be requested from the 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 the 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 are funded in annual increments called budget periods. The length of an initial project period (competitive segment) or of any subsequent competitive segment is determined by the NIH 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 solely 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 also will reflect any remaining future-year commitments. NIH may decide to withhold support for one or more of the reasons cited in "Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support." A grantee may appeal this decision only if the withholding was for the grantee's failure to comply with the terms and conditions of a previous award (see "Administrative Requirements—Grant Appeals Procedures").

Budget

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

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 cash request on an advance or reimbursement basis, as specified in the NGA and as described in this section. Payments under NIH grants are generally made as advance payments. Except as indicated in this section, 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 work day 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 work day after they are received, and immediately returning all undisbursed Federal funds to PMS.

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

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 III).

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.

Cash Request

Grantees not eligible for an unrestricted advance of funds by SMARTLINK II/ACH or CASHLINE/ACH are financed on the basis of submission of a cash request, usually monthly. The cash request may be on either an advance or reimbursement basis, as specified by the NIH awarding office. Cash requests are used 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 also may be converted from an unrestricted advance payment method to a cash request basis if, during postaward administration, the GMO determines that a grantee is not complying with the cash management requirements or other requirements of the award(s), 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 governments 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 budget request is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of recipient and the type of award. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the grantee may need to modify its award budget during performance 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 GMO monitors expenditures for conformance with cost policies. The GMO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports. The GMO also may use audit findings as the basis for final cost adjustments (see "Administrative Requirements—Closeout").

This section addresses the general principles underlying the allowability of costs, differentiates direct costs from F&A (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 the 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. The cost principles apply to all NIH grants, award mechanisms, and special programs and authorities, including modular awards and awards under SNAP with one exception: they are not applicable to NIH fellowship awards. The allowable use of funds under NIH fellowships is included in "National Research Service Awards."

- 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[12]
- 45 CFR Part 74, Appendix E—Cost Principles for Hospitals
- 48 CFR Subpart 31.2 (*Federal Acquisition Regulation*)—Cost Principles for Commercial 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 organizational 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.

[12]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.

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. Subpart B of this part contains additional information on allowability of costs for particular types of grants/grantees/activities.

Direct Costs and Facilities and Administrative (Indirect) Costs[13]

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

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[13] 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."

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 in this subsection, NIH will not reimburse F&A costs unless the grantee has established an F&A cost (indirect cost) rate covering the applicable activities and period of time. These rates are negotiated by the Division of Cost Allocation (DCA), HHS, the Office of Acquisition Management and Policy (OAMP), NIH (responsible for negotiating F&A cost rates for for-profit entities receiving awards from HHS), or other agency with cognizance for F&A cost rate (and other special rate) negotiation. If an applicant is advised by the GMO of the need to establish a rate, the GMO will indicate the responsible office to be contacted.

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,[14] which may be obtained from DCA, provide guidance on preparing F&A cost[15] 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 OAMP (see Part III). DCA should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of OMB Circular A-21.

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

F&A costs awarded may be subject to upward or downward adjustment, depending on the type of rate negotiated, and grantees may rebudget between direct and F&A costs (in either direction) without NIH prior approval, provided there is no change in the scope of the approved project.

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[14] 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, still may be used as guidance.

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

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

There are awards that require negotiation of project costs annually, e.g., General Research Clinical Centers (GCRCs), clinical trials, and Primate Research Center Grants (P51s). For these awards, these policies pertain to each year of support rather than to a multi-year competitive segment.

Once NIH awards a grant, it is not obligated to make any supplemental or other award for additional F&A costs or for any other purpose. There are limited circumstances under which the GMO may award F&A costs where none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for F&A costs because the applicant or grantee did not submit a timely F&A cost proposal and the grantee subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for F&A costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the F&A costs applicable to the period after the date of the grantee's F&A cost proposal submission. This provision does not affect local 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 "Awards to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components."

- **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 cost rate include:

- **Research training grants and career awards:** F&A costs under research training grants and career awards will be funded at a rate of 8 percent of total direct costs, exclusive of tuition and fees and expenditures for equipment. State and local government agencies, except State universities or hospitals, may receive full F&A cost reimbursement under NIH research training grants and career awards.

- **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 should 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 organizational official of the grantee, consortium participant, or contractor. An explanation merely stating that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. Transfers of costs from one 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 also may require a grantee to take corrective action by imposing additional terms and conditions on an award(s).

The GMO monitors grantee expenditure rates within each budget period and within the overall project period 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, unobligated 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.

A grantee may allocate costs normally assignable to multiple projects to one of those projects or else to treat multiple projects as a single cost objective regardless of the funding IC or whether the awards involve the same or different PIs, if it obtains NIH prior approval for this "closely related work." When multiple ICs are involved, the request for approval should be submitted to the designated GMO of each of the affected ICs. NIH will use the following criteria in reviewing such requests:

- 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.

In addition, recipients of NIH awards under the Federal Demonstration Partnership (FDP) may be permitted, with the approval of NIH and the other funding agency(ies), to treat related projects funded by NIH and another agency(ies) 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 Reports.") The NIH awarding office will notify the grantee of any additional actions that may be necessary.

Services Provided by Affiliated Organizations

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

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

- The grantee foundation is charged for, and is legally obligated to pay for, the services provided by the parent organization.

- The affiliated organizations are subject to 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.

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

Allowability of Costs/Activities

The governing cost principles address selected items of cost, some of which are mentioned in this subsection for emphasis. The cost principles themselves should be consulted for the complete explanation of the 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 designated 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 type of 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") 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, as applicable. Individual A&R projects exceeding $500,000 will be subject to the requirements specified in the "Construction Grants" section.

Routine maintenance and repair of the organization's physical plant or its equipment, which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this NIH 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 purpose 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 result in a change in scope. If the rebudgeting results in an A&R project exceeding $300,000, NIH will consider the rebudgeting to be a change in scope, and the grantee must submit to the NIH IC the documentation specified in "Construction Grants" for approval of A&R projects above that dollar level.

Animals: Allowable for the acquisition, care, and use of experimental animals. If the grantee operates an animal resource facility, charges for use of the facility should be determined in accordance with the *Cost Analysis and Rate Setting Manual for Animal Resource Facilities* (May 2000), available from the National Center for Research Resources (NCRR) at its Web site: (http://www.ncrr.nih.gov/newspub/CARS.pdf) or from the NCRR Office of Science Policy and Public Liaison, 6705 Rockledge Drive, Bethesda, MD 20892-7965, (301) 435-0888, e-mail: ospio@ncrr.nih.gov.

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 proportional basis, and this practice is followed consistently by the grantee. Otherwise, charges for audits should be treated as F&A costs.

Bad Debts: Unallowable.

Bid and Proposal Costs: Allowable as an F&A cost. See 45 CFR 74.27(b)(1) for policy for nonprofit 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 also may be charged to the grant. (Also see "Construction Grants—Allowability of Costs/Activities.")

Child Care Costs: Allowable if incurred to assist individuals to participate as subjects in research projects. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see "Fringe Benefits" in this subsection).

Communications: Allowable. Such costs include local and long-distance telephone calls, telephone surveys, telegrams, and postage, and are usually treated as F&A costs.

Conference Grant Costs: See "Support of Scientific Meetings (Conference Grants)" 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 "Consortium Agreements" for policies that apply to grantee collaboration with other organizations in carrying out the grant-supported research.)

Construction: Allowable only when program legislation specifically authorizes new construction, modernization, or major A&R, and NIH specifically authorizes such costs in the NGA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy (see "Construction Grants").

Consultant Services: Allowable. A consultant is an individual retained to provide professional advice or services on a project for a fee but usually not as an employee of the requiring organization. The term "consultant" also includes a firm that provides paid professional advice or services. Grantees must have written policies governing their use of consultants that are consistently applied regardless of the source of support. The general circumstances of allowability of these costs, which may include fees and travel and subsistence costs, are addressed in the applicable cost principles under "professional services costs."

In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee as long as those separate services are not related to the same project and are not charged to the same project. 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. **Under no circumstances can an individual be paid as a consultant and an employee under the same NIH grant.**

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" 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 non-construction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see "Reserve Funds" in this subsection). (See "Construction Grants—Allowability of Costs/Activities—Allowable Costs/Activities" 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 "Awards to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components—Allowability of Costs/Activities" for the allowability of these costs under awards to those types of organizations.)

Depreciation or Use Allowances: Allowable. Such costs are usually treated as F&A costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable.

Donor Costs: Allowable for payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related.

Drugs: Allowable if within the scope of an approved research project.

Project funds may not be used to purchase drugs classified by 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 organizational policy consistently applied regardless of the source of funds.

Entertainment Costs: Unallowable. This includes the cost of amusements, social activities, and related incidental costs.

Equipment: Allowable for purchase of new, used, or replacement equipment as a direct cost or as part of F&A costs, depending on the intended use of the equipment. NIH prior approval may be required as specified in "Administrative Requirements—Changes in Project and Budget."

In accordance with the requirements of NIH appropriations acts, American-made items should be purchased to the extent possible.

Funds provided under a conference grant may not be used 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 "Grants to Federal Institutions and Payments to (or on Behalf of) Federal Employees Under Grants—Allowability of Costs/Activities" 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 NIH IC.

Fringe Benefits: Allowable as part of overall compensation to employees in proportion to the amount of time or effort employees devote to the grant-supported project, provided such costs are incurred under formally established and consistently applied policies of the organization (see "Salaries and Wages" in this subsection).

Tuition or tuition remission for regular employees is allowable as a fringe benefit. For organizations subject to OMB Circular A-21, tuition benefits for family members other than the employee are unallowable. For policies applicable to tuition remission for students working on grant-supported research projects, see "Salaries and Wages" in this subsection. See "National Research Service Awards—Individual National Research Service Awards (Fellowships)—Financial Provisions—Other Costs—Tuition and Fees" and "National Research Service Awards—Institutional National Research Service Awards (Training Grants)—Financial Provisions—Other Direct Costs—Trainee Tuition and Fees" 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."

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 a fringe benefit (see "Fringe Benefits" in this subsection). See "National Research Service Awards—Individual National Research Service Awards (Fellowships)—Other Terms and Conditions—Leave" and "National Research Service Awards—Institutional National Research Service Awards (Training Grants)—Other Terms and Conditions—Leave" for NIH policy on leave for fellows and trainees.

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 designated 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 designated GMO if it intends to engage in these activities. (Also see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying" and "Administrative Requirements—Monitoring—Reporting" concerning lobbying restrictions 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 employees or their beneficiaries) in lieu of the method described above. Under this method, the benefits may be charged in the grantee's fiscal year in which the payments are made to, or on behalf of, retired employees or their beneficiaries, provided that the grantee follows a consistent policy of treating such payments as expenses in the year of payment. See the applicable cost principles for additional information on the allowability of costs associated with pension plans.

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 the grant, if awarded, without NIH 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 direct costs but should be treated as F&A costs if they benefit more than one sponsored agreement or if they benefit the grant and other work of the organization.

Publications: Allowable. Page charges for publication in professional journals 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, also are 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, Intellectual Property Rights, and Sharing Biomedical 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 (also see "Travel" and "Relocation Costs" in this subsection.

Registration Fees (for Symposiums and Seminars): Allowable if necessary to accomplish project objectives.

Relocation Costs: Allowable—in other than change of grantee organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the grantee's benefit rather than the individual's, and 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 costs that may be charged to NIH projects generally may not exceed the amount that would be allowed if the grantee continued to own the property.

Rental costs under less-than-arms-length leases are allowable only up to the amount that would be allowed under the applicable cost principles had title to the property been vested in the grantee. A "less-than-arms-length" lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), 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 individuals, including patients and volunteers, participating in research programs are allowable. For grants that are not subject to expanded authorities (see "Administrative Requirements—Changes in Project and Budget"), NIH prior approval always is required to incur patient care costs if not previously approved by NIH, to rebudget additional funds into, or to rebudget funds out of the research patient care costs category. For grants subject to expanded authorities, NIH prior approval is required only if the incurrence of patient care costs represents a change in scope.

"Routine services" include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made. "Ancillary services" are those special services for which charges 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" for NIH policy concerning reimbursement of these costs.

The following otherwise allowable costs are not classified as research patient care costs: items of personal expense reimbursement, such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors. Such costs should be included in the "Other Expenses" category of the grant budget.

Reserve Funds: Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see "Contingency Funds" in this subsection).

Sabbatical Leave Costs: Sabbatical leave costs may be included in a fringe benefit rate or in the organization's F&A rate. Salary may be charged directly to a project for services rendered to the project by individuals while they are on sabbatical leave, provided the salary is proportional to the service rendered and is paid according to established organizational policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of that individual's regular salary from his or her organization.

Salaries and Wages: Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project. Compensation costs are allowable to the extent that they are reasonable; conform to the established policy of the organization consistently applied regardless of the source of funds; and reflect no more than the percentage of time actually devoted to the NIH-funded project. As required in its annual appropriations act, NIH will not reimburse grantees for the direct salaries of individuals at a rate in excess of the level specified in the appropriations language. Direct salary is exclusive of fringe benefits and F&A costs. This salary limitation does not apply to consultant payments or to contracts for routine goods and services but does apply to consortium participants (see "Consortium Agreements").

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 also must 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 organizational 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 under research grants (including fellows and trainees) are allowable, provided:

- The individual is performing activities necessary to the grant;
- Tuition remission and other forms of compensation are provided in accordance with established institutional policy, consistently provided to students performing similar activities conducted in non-sponsored as well as in sponsored activities; and
- During the academic period, the student is enrolled in an advanced degree program at a grantee or affiliated institution and the activities of the student in relation to the federally sponsored research project are related to the degree program.

Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages are subject to the reporting requirements in section J.8. of OMB Circular A-21, or an equivalent method for documenting the individual's effort on the research project. Tuition remission may be charged on an average rate basis. NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of OMB Circular A-21 and its current operating guidelines.

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 research training grants and fellowships. These payments are made according to a pre-established 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—Individual National Research Service Awards (Fellowships)—Financial Provisions—Stipends—Stipend Supplementation" and "National Research Service Awards—Institutional National Research Service Awards (Training Grants)—Financial Provisions—Stipends—Stipend Supplementation." Stipends are not allowable under research grants even when they appear to benefit the research project.

Subject Costs: See "Research Patient Care" in this subsection.

Supplies: Allowable.

Taxes: Allowable. Such costs include taxes that an organization is required to pay as they relate to employment, services, travel, rental, or purchasing for a project. Grantees must avail themselves of any tax exemptions for which activities supported by Federal funds may qualify. State sales and use taxes for materials and equipment are allowable only when the State does not grant a refund or exemption on such taxes.

Termination or Suspension Costs: Unallowable except as 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 NIH IC.

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—Institutional National Research Service Awards (Training Grants)—Financial Provisions—Other Direct Costs" 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, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile.

Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the U.S. and its possessions 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 those 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. The cost of travel under a ticket issued by a U.S. flag air carrier that leases space on a foreign air carrier under a code-sharing agreement is allowable if the purchase is in accordance with GSA regulations on U.S. flag air carriers and code shares (http://www.policyworks.gov/org/main/mt/homepage/mtt/ftr/newftr/301-10_134.html). (A code-sharing agreement is an arrangement between a U.S. flag carrier and a foreign air carrier in which the U.S. flag carrier provides passenger service on the foreign air carrier's regularly scheduled commercial flights.)

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

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

ADMINISTRATIVE REQUIREMENTS

Changes in Project and Budget

In general, NIH grantees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of 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 grantee-initiated changes that may be made under the grantee's authority and the changes that require NIH approval are outlined below and in Subpart B with respect to particular types of awards, activities, or recipients. In addition, individual awards may restrict grantees' authorities to make budget and project changes without NIH prior approval. If NIH approval is required, it must be requested of, and obtained from, the designated NIH GMO in advance of the change or obligation of funds as specified below under "Requests for Approval."

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

Prior Approval Requirements

The following table (Table II-2) applies to NIH research grants and cooperative agreements to domestic organizations. See Part B for prior approval requirements that apply to other types of awards and recipients. The table lists the activities and/or expenditures that require GMO prior approval in accordance with the general terms and conditions of award (i.e., expanded authorities, Federal Demonstration Partnership (FDP), or the terms and conditions of this policy statement) and also includes activities and/or expenditures where NIH has waived the prior approval requirement on a class basis. The information in this table is for guidance purposes only. Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to the designated GMO.

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TABLE II-2
SUMMARY OF ACTIONS REQUIRING NIH PRIOR APPROVAL

Activity or Expenditure Requiring NIH Prior Approval	Expanded Authorities[16] (effective 12/94)	Federal Demonstration Partnership (FDP)[17] (effective 7/00)	NIH Grants Policy Statement (NIHGPS) (effective 3/01)
Change in scope	YES	YES	YES
Preaward costs (more than 90 days prior to effective date of a new or competing continuation award)	YES	YES	YES
Preaward costs for non-competing awards	At grantee's own risk	At grantee's own risk	At grantee's own risk
Change in key personnel	YES	YES	YES
Change of grantee organization	YES	YES	YES
Change in grantee organizational status	YES	YES	YES
Addition of a foreign component under a grant to a domestic organization	YES	YES	YES
Changes to award terms and conditions or undertaking any activities disapproved or restricted as a term of award	YES	YES	YES
Carryover of unobligated balances from one budget period to the next	NO	NO	YES
Extension of final budget period of a project period	NO: one extension up to 12 months allowed with no additional funds. Must notify IC no later than 10 days prior to expiration.	NO: one extension up to 12 months allowed with no additional funds. Must notify IC no later than 10 days prior to expiration.	YES

[16] The following mechanisms are routinely included in EA/FDP: P01s, Ks, and all Rs except R43 and R41.

[17] The following mechanisms are routinely included in EA/FDP: P01s, Ks, and all Rs except R43 and R41.

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Activity or Expenditure Requiring NIH Prior Approval	Expanded Authorities[16] (effective 12/94)	Federal Demonstration Partnership (FDP)[17] (effective 7/00)	NIH Grants Policy Statement (NIHGPS) (effective 3/01)
Equipment purchases exceeding $25,000/unit, regardless of amount of NIH funds involved	NO, unless change in scope	NO, unless change in scope	YES
Retention of research grant funds when career (K) award made	YES	YES	YES
Alteration and renovation (A&R) (rebudgeting into A&R costs exceeding 25 percent of total approved budget for a budget period)	NO, up to (and including) $300,000 YES, if>$300,000	NO, up to (and including) $300,000 YES, if>$300,000	NO, up to (and including) $300,000 YES, if>$300,000
Transferring amounts from trainee costs	YES	YES	YES
Capital expenditures (construction, land or building acquisition)	YES	YES	YES
Need for additional NIH funding	YES	YES	YES
Closely related work	YES	YES	YES
Transfer of funds between construction and non-construction work	YES	YES	YES
Program income (use of any alternative other than that specified by NIH)	NO	NO	YES
Transferring performance of substantive programmatic work to a third party (by consortium agreement, contract, or other means)	NO, unless change in scope or the third party is a foreign organization or component	NO, unless change in scope or the third party is a foreign organization or component	YES
Incurrence of patient care costs (if not previously approved or rebudgeting additional funds into or rebudgeting funds out of this category)	NO, unless change in scope	NO, unless change in scope	YES

For the following categories or types of actions (and those in Table II-2), prior approval is required whether or not the change has a budgetary impact.

Change in Scope: In general, the PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the grantee must obtain prior approval from 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. However, as noted, certain actions in the following list always require NIH prior approval under the circumstances specified.

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.
- A clinical hold by FDA under a study involving an IND or an IDE
- Applying a new technology, e.g., 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. If the third party is a foreign component, this prior approval requirement also applies to grants subject to expanded authorities** (see "Expanded Authorities" in this subsection).
- Change in key personnel (see "Change in Status, Including Absence, of Principal Investigator and Other Key Personnel" for requirements for NIH approval of alternate arrangements for or replacement of key personnel).
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. For example, if the award budget for total costs is $200,000, any rebudgeting that would result in an increase or decrease of more than $50,000 in a budget category is be considered "significant rebudgeting." The base used for determining significant rebudgeting excludes the effects of prior year carryover balances but includes competing and noncompeting supplements.

- 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" in this subsection).

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 biographical sketch of the individual proposed, other sources of support, and any budget changes resulting from the proposed change. If the arrangements proposed by the grantee, including the qualifications of any proposed replacement, are not acceptable to 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 designated 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 that involves the transfer of a grant to or between foreign institutions or international organizations requires competitive review and approval of the IC Advisory Coun-

cil/Board. Transfer of a grant from a foreign organization to a domestic organization requires the approval of the GMO.

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

A request for a change of grantee organization must be submitted to the designated GMO and must be accompanied by a Relinquishing Statement and a Final Invention Statement and Certification from the original grantee as well as an application (PHS-398) from the proposed grantee. If the original award was the result of a modular application, modular procedures also apply to the request for change of grantee. The application (for awards other than those made under modular procedures) 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;
- Certification of IRB/IACUC approval, 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.

For a modular application, the proposed grantee must submit the following:

- A face page;

- Narrative budget information, including total direct costs and F&A costs for the current budget period;
- Biographical sketches for key personnel;
- "Other support" pages;
- Resource page;
- Checklist page; and
- If future budget periods remain, information regarding the number of modules and the basis for computing F&A costs.

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 administrative 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 previously committed direct cost level plus applicable F&A costs). This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward.

Change in Grantee Organizational Status: Grantees must 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."

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 organizational 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 or-

ganization, 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: Adding a 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 generally is allowable without prior approval under expanded authorities unless restricted (see "Expanded Authorities" in this subsection).

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 designated GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests are usually for a period of up to 12 months, based on a need to provide continuity of project activities while a competing continuation application is being reviewed or to permit orderly phaseout of project activities for which there will be no further NIH support, and may request 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 generally do not apply under expanded authorities with respect to a "no-cost" extension of the final budget period of a project period** (see "Expanded Authorities" in this subsection).

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

Retention of Research Grant Funds When a Career (K) 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 a career (K) award 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—Administrative Requirements—Prior Approval Requirements—Alteration and Renovation Projects under Non-construction Grants" 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—Institutional National Research Service Awards (Training Grants)—Financial Provisions—Rebudgeting of Funds").

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

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

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 prior approval of those expenditures and activities specified in this subsection and has provided the authorities (hereafter "expanded authorities") to grantees to take such actions without NIH prior approval. 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 Awards).

NIH ICs also may 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 also may be excluded from expanded authorities. This may include grants or grantees that require closer project monitoring or technical assistance, such as clinical trials and certain large multi-project grants. If excluded, the NGA will indicate this change from the standard terms and conditions. In addition, one or more of these authorities may be overridden by a special term or condition of the award. Therefore, grantees must review the NGA to determine whether and to what extent they are permitted to use expanded authorities. 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 NIH awarding office, there will be no change in the project's originally approved scope, 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 project period through this process, the grantee agrees to update all required certifications, including human subjects and animal welfare, in accordance with applicable regu-

lations and policies. Grantees may not extend project periods previously extended by the NIH awarding office. Any additional project period extension beyond the one-time extension of up to 12 months requires NIH prior approval. (See "Prior Approval Requirements" in this section for extensions requiring additional funds.)

Carryover of Unobligated Balances: Except for funds restricted in an NGA, unobligated funds remaining at the end of a budget period are automatically carried over. 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 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 applies to awards subject to expanded authorities unless the NGA specifies another alternative or the grantee is a for-profit organization other than an SBIR/STTR awardee. For-profit organizations other than SBIR/STTR awardees are subject to the deductive alternative (see "Administrative Requirements—Management Systems and Procedures—Program Income").

Transferring the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement, Contract, or Other Means: Under expanded authorities, a grantee is not required to obtain NIH prior approval for transferring the performance of substantive programmatic work **unless** the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

Cost-Related Prior Approvals, Including Patient Care and Equipment: Requirements for NIH approval of incurrence of these individual costs, including rebudgeting for them, do not apply under expanded authorities **unless** they constitute a change in scope.

Requests for Approval

All requests for NIH awarding office prior approval must be made, in writing (which includes submission by e-mail) to the designated GMO no later than 30 days before the pro-

posed change. The request must be signed by both the PI and the authorized organizational official. Failure to obtain prior approval, when required, from the appropriate NIH awarding office may result in the disallowance of costs, termination of the award, or other enforcement action within NIH's authority.

E-mail requests must be clearly identified as prior approval requests and reflect the complete grant number in the subject line, and they should be sent to the GMO that signed the NGA. E-mail addresses for NIH staff can be obtained from the NIH Directory and E-Mail Forwarding Services at http://directory.nih.gov. E-mail requests must include the name of the initiating PI, grantee name, the PI's telephone number, fax number, and e-mail address, and must be transmitted to NIH by the authorized organizational official, who must include comparable identifying information. If the entire message of the request cannot be included in the body of the e-mail, the request should be submitted to NIH in hard copy.

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

Whenever grantees contemplate rebudgeting or other 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, 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. 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 FDP) 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) (see "Administrative Requirements—Changes in Project and Budget—Expanded Authorities").

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 trials, high-risk grantees, certain large individual or multi-project 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 or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and negotiations, if applicable, 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. If there is a change in performance site and/or anticipated program income, grantees also must submit the PHS-2590 checklist and, if program income is anticipated, the application should reflect the estimated amount and source of the income. Grantees (other than foreign grantees and Federal institutions) also are 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, a significant change in the level of effort for key personnel from what was approved for this project? A "significant change" is a 25 percent or greater reduction in time devoted to the project. If so, the grantee must explain; if not, the grantee must so state.

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

The 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 or-

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

For awards under SNAP (other than awards to foreign organizations or Federal institutions), a Financial Status Report (FSR) 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"). Foreign organizations and Federal institutions must submit an annual FSR even if an award is under SNAP. (Also see "Administrative Requirements—Monitoring—Reporting—Financial Reports.")

Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical 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, and to effect their timely transfer to industry for commercialization. If research findings result in inventions, grantees have the right to retain title to these inventions, as long as they abide by the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR 401, for their utilization, commercialization, and public availability. In general terms, these regulations encourage grantees to utilize patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, when an invention is useful primarily as research tool, technology transfer, in the form of journal articles or other publications or through the dissemination of research products or resources, may be a more appropriate means of promoting utilization, commercialization, or public availability of an invention.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of biomedical 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,[18] 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

[18] 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.

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 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").

Sharing Biomedical Research Resources

NIH has published "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources" (64 FR 72090, December 23, 1999). The purpose of these guidelines is to assist recipients in determining reasonable terms and conditions for disseminating research tools as well as for acquiring research tools, consistent with the objectives of furthering biomedical research and adhering to the requirements of the Bayh-Dole Act (see "Inventions and Patents" in this subsection) and the terms and conditions of their NIH awards.

Organizations that receive NIH grants or cooperative agreements (or contracts) have an obligation to preserve research freedom, safeguard appropriate authorship, and ensure timely disclosure

of their scientists' research findings by such means as publications and presentations at scientific meetings. Recipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish, or that automatically grant co-authorship or copyright to the provider of an invention used primarily as a research tool. NIH also recognizes the need for reasonable restrictions on collaboration by academic researchers involved with an industrial partner that avoid conflicting obligations to other industrial partners.

NIH expects recipients to determine the appropriate means of effecting prompt and effective access to research tools (including inventions for which patents and exclusive licenses are inappropriate) to further advance scientific research and discovery. If further research, development, and private investment are not necessary to realize the primary usefulness of a research tool, publication, deposit in an appropriate databank or repository, widespread non-exclusive licensing, or other dissemination techniques may be appropriate. For example, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories.

Investigators are expected to submit unique biological information to the appropriate data banks; 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. Categories of these resources include, but are not limited to, 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.

Organizations and investigators may charge the requester for the reasonable cost of production of unique biological materials and for packing and shipping. Such costs may include the costs of personnel, supplies, and other directly related expenses. Investigators should note that income earned from these charges is considered and needs to be accounted for as program income (see "Administrative Requirements—Financial Management System Standards—Program Income"). This should not be an impediment to the distribution of materials.

If additional non-Federal involvement is needed to assist with maintenance, reproduction, and/or distribution of the research tool, or if further research and development are needed to realize the usefulness of an invention as a research tool, licensing terms should be developed that ensure widespread and appropriate dissemination of the final tool product.

Recipients of NIH grants should adopt streamlined procedures for disseminating research tools, including transfer of materials developed with NIH funds to for-profit organizations for internal use by those organizations (as opposed to commercial development and sale or provision of services). Grantees also should develop and implement clear policies articulating acceptable conditions for acquiring research resources. Examples of these policies can be found in the guidelines cited above.

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.

Any question regarding this policy or the treatment of income should be directed to the designated GMO.

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 here and also may 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 busi-

ness 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 co-inventors (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 also is 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 I, Room 1136, 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 organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Grantees may use their existing systems to manage NIH grant funds and activities as long as they are consistently applied regardless of the source of funds and meet the standards and requirements set forth in 45 CFR Part 74 or 92 and 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, as necessary, including, but not limited to, the use of special terms and conditions. NIH also will oversee the performance of the grantee's systems as part of its routine postaward monitoring. The grantee's systems also are subject to audit (see "Administrative Requirements—Monitoring—Audit").

NIH seeks to foster within grantee organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative, written policies and procedures, training, management controls and other internal controls, performance assessment, administrative simplifications, and information sharing.

Financial Management System Standards

Grantees are required to meet the standards and requirements for financial management systems set forth or referenced in 45 CFR 74.21 or 92.20, as applicable. The standards and requirements for a financial management system are essential to the grant relationship. NIH cannot support the research unless it has assurance that its funds will be used 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 obligation and expenditure of funds. Grantees must notify NIH when problems are identified.

A grantee's failure to establish adequate control systems constitutes a material violation of the terms of the award, 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 in this subsection. Accountability refers to whether NIH will specify how the income is to be used and whether the income needs to be reported to NIH and for what length of time. Unless otherwise specified in the terms and conditions of the award, NIH grantees are not accountable for program income accrued after the period of grant support.

Consortium agreements and contracts under grants are subject to the terms of the agreement or contract with regard to the income generated by the activities, but the terms specified by the grantee must be consistent with the requirements of the grant award. Program income must be reported by the grantee as discussed in this subsection.

Program income earned during the period of grant support (other than income earned as a result of copyrights, patents, or inventions or as a result of the sale of real property, equipment, or supplies) shall be retained by the grantee and may be used in one or a combination of the alternatives indicated in Table II-3 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 research resources.

NIH may require an different use of program income than that indicated in Table II-3 if a grantee has deficient systems or the PI has a history of frequent, large annual unobligated balances on previous grants or has requested multiple extensions of the budget/project period. Regardless of the alternative applied, program income may be used only for allowable costs, in accordance with the applicable cost principles and the terms and conditions of the award.

TABLE II-3
REQUIREMENTS FOR PROGRAM INCOME ACCOUNTABILITY

Program Income Alternative	Use of Program Income	Applicability
Additive Alternative	Added to funds committed to the project or program and used to further eligible project or program objectives.	Applies to NIH awards subject to expanded authorities and to awards under the SBIR/STTR programs, unless the terms and conditions of the award specify the use of another alternative.
Deductive Alternative	Deducted from total allowable costs of the project or program to determine the net allowable costs on which the Federal share of costs will be based.	Applies to NIH awards issued to non-SBIR/STTR for-profit organizations and to other awards if specified in the terms and conditions of award.
Combination Alternative	Uses all program income up to (and including) $25,000 as specified under the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative.	Applies to all other awards, unless the terms and conditions of the award indicate otherwise.
Matching Alternative	Used to satisfy all or part of the non-Federal share of a project or program.	Available for use by NIH programs that require matching.

Sale of Real Property, Equipment, and Supplies

The requirements that apply to the sale of real property are addressed in "Construction Grants." For equipment and supplies purchased under NIH grants for basic or applied research by non-profit institutions of higher education or non-profit organizations whose principal purpose is the conduct of scientific research, the grantee is exempt from any requirement to account to NIH for proceeds from the sale of the equipment or supplies; however, NIH has certain rights with respect to such property as specified in "Administrative Requirements—Management Systems and Procedures—Property Management System Standards."

All other types of grants/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 also are subject to the requirements in 45 CFR 74.35 or 92.33 with respect to the use or sale of unused supplies. If the grantee retains the supplies for use on other than federally sponsored activities, an amount is due NIH as if they were sold.

Reporting of Program Income

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, for which there may be no accountability or which will be reported separately), the amount earned and the amount expended must be reported on the FSR (SF-269—Long Form). 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 must be reported on lines 10r and 10s, as appropriate, of the FSR (SF-269); program income subject to the deductive alternative must be reported on lines 10c and 10q of the FSR (SF-269); and program income subject to the matching alternative must be reported on lines 10g and 10q of the FSR (SF-269). (See "Administrative Requirements—Monitoring—Reporting.") For awards under SNAP, the amount of program income earned must 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 must 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 must be reflected as a credit to the grant on line 10c of the FSR (SF-269).

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, Intellectual Property Rights, and Sharing Biomedical 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[19], 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., which 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 in advance of the acquisition. The grantee also must follow appropriate procurement procedures in acquiring property as specified in "Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements."

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[19] 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.

Recipients of NIH grants other than Federal institutions cannot be authorized to use Federal supply sources.

Real Property

See "Construction Grants—Administrative Requirements—Real Property Management Standards" for requirements that apply to the acquisition, use, and disposition of real property. Fixed equipment that is part of a construction grant is subject to those requirements.

Equipment and Supplies

In general, title to equipment and supplies acquired by a grantee with NIH funds vests in the grantee upon acquisition, subject to the property management requirements of 45 CFR 74.31, 74.34, 74.35, and 74.37, or 92.32 and 92.33. Limited exceptions to these general rules are States, which 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. 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 equipment with an acquisition cost of $5,000 or more to the Federal Government or to an eligible third party named by the NIH awarding office under the conditions specified in 45 CFR 74.34(h). NIH may exercise this right within 120 days of the completion or termination of an award or within 120 days of receipt of an inventory, as provided in 45 CFR 74.34(h)(2), whichever is later.

NONEXEMPT PROPERTY

All other equipment and supplies acquired under all other NIH grant-supported projects by any other type of grantee are subject to the full range of acquisition, use, management, and disposition requirements of 45 CFR 74.34 and 74.35, or 92.32 and 92.33. Property acquired or used under an NIH grant-supported project, including any federally owned property, also is subject to the requirements for internal control specified in 45 CFR 74.21 or 92.20, 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:

- Records that adequately identify (according to the criteria specified in the regulations) items of equipment owned or held by the grantee and state the current location of each item.

- A physical inventory of the equipment, at least once every 2 years, to verify that the items covered by the records exist and are either usable and needed or listed as surplus. A statistical sampling basis is acceptable.

- 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. The revocable license agreement between NIH and the grantee provides for the transfer of the equipment for the period of grant support under the following conditions:

- Title to the property remains with the Federal Government.

- NIH reserves the right to require the property to be returned to the Federal Government should it be determined to be in the best interests of the Federal Government to do so.

- The use to which the grantee puts the property does not permanently damage it for Federal Government use.

- The property is controlled and maintained in accordance with the requirements of 48 CFR 45.5 (the *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."

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 responsibility for the direction of the project and accountability to the Government. Therefore, the agreement shall 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 IC 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 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" (now "simplified acquisition 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, or, 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 as a result of 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 also are expected to publish and provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities as specified in "Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical 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 in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of expanded authorities, or conversion to a reimbursement payment method (also see "Administrative Requirements—Enforcement Actions").

Progress Reports as Part of Noncompeting Continuation Requests

Progress reports usually are 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 NIH awarding office will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, and non-construction activities.

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 SF-269 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. An annual FSR is required for awards to foreign organizations and Federal institutions, whether or not they under SNAP. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the close of the budget period. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NGA will specify both the frequency and due date.

For domestic awards under SNAP, in lieu of the annual FSR, NIH will use the quarterly FCTR (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[20] 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 organizational 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.

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[20] Information about the electronic transmittal of FSRs may be obtained from OFM, NIH, at (301) 402-9123.

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 should be done as promptly as possible but no later than 1 year from the due date of the original report, i.e., 15 months following the end of the budget period (or competitive segment for awards under SNAP).** If an adjustment is to be made, the NIH awarding office will advise the grantee of actions it will take to reflect the adjustment. NIH will not accept any revised report received after that date and will return it to the grantee.

Invention Reporting

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 organizational 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, Intellectual Property Rights, and Sharing Biomedical 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 also 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 research misconduct 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—Research Misconduct").

Lobbying Disclosure

For awards subject to the anti-lobbying requirements described in "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying," grantees 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 action.

Record Retention and Access

Grantees generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FSR is submitted. For awards under SNAP (other than those to foreign organizations and Federal institutions), the 3-year retention period will be calculated from the date the FSR for the entire competitive segment is submitted. Those grantees must retain the records pertinent to the entire competitive segment for 3 years from the date the FSR is submitted to NIH. Foreign organizations and Federal institutions are required to submit annual FSRs for all awards, including those under SNAP, and must retain these records for a period of 3 years from the date of submission of the annual FSR to NIH. See 45 CFR 74.53 and 92.42 for exceptions and qualifications to the 3-year retention requirement. 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 in a timely manner, fairly and accurately.
- The entity has complied with applicable laws, regulations, and other grant terms.
- 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) and in this policy statement (for types of organizations to which OMB Circular A-133 does not directly apply). In general, OMB Circular A-133 requires a State government, local government or non-profit organization (including institutions of higher education) that expends $300,000 or more per year in Federal grants, cooperative agreements, and/or procurement contracts to have an annual audit by a public accountant or a Federal, State, or local government audit organization that meets the standards specified in generally accepted government auditing standards (GAGAS). The audit requirements for foreign grantees and for-profit grantees are addressed in the sections of this policy statement that provide specific requirements for those types of grantees.

When a grantee procures audit services, the procurement must comply with the procurement standards of 45 CFR Part 74 or 92, as applicable, including obtaining competition and making positive efforts to use small businesses, minority-owned firms, and women's business enterprises. Grantees should ensure that comprehensive solicitations, made available to interested firms, include all audit requirements and specify the criteria to be used for selection of the firm, 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 expending $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 expending 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 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
  1201 E. 10th Street
  Jeffersonville, IN 47132

If the schedule of findings and questioned costs discloses an audit finding related to an HHS/NIH award or the schedule of prior audit findings reports the status of any audit finding relating to an HHS/NIH award, the Federal audit clearinghouse will provide copies of the audit report to the National External Audit Review Center (NEARC), Office of the Inspector General, HHS. NEARC will, in turn, distribute them within HHS for further action, as necessary. **Audit reports should not be sent directly to the GMO.**

Recipients must follow a systematic method for ensuring timely and appropriate resolution of audit findings and recommendations, whether discovered as a result of 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 if the adverse determination is of a type covered by the NIH/HHS grant appeals procedures (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.

It is imperative that grantees submit required OMB Circular A-133 audits within the time limits specified in the Circular. If grantees are delinquent in complying with the provisions of A-133, HHS/NIH will impose sanctions that may result in the loss of Federal funds. No audit costs will be allowed either as F&A costs or direct costs to Federal awards if the required audits have not been completed or have not been conducted in accordance with the provisions of OMB Circular A-133.

See "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 research misconduct, may cause NIH to take one or more enforcement actions, de-

pending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies, and generally will 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 may take actions designed to prevent future noncompliance, such as closer monitoring. If NIH imposes sanctions on a grantee as a result of research misconduct or will more closely monitor an award(s) through the use of special conditions, NIH will share this information with other HHS components.

Modification of the Terms of Award

During grant performance, the designated GMO may impose special conditions to require correction of identified financial or administrative deficiencies. At the time the special conditions are imposed, the GMO will notify the grantee of the nature of the conditions; the reason why they are being imposed; the 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 also may, 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 a reasonable basis to conclude that the PI or other key personnel are no longer qualified to perform in that capacity, it 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 also may be terminated, partially or totally, by the grantee or by NIH with the consent of the grantee. If the grantee decides to terminate a portion of a grant, NIH may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, NIH will advise the grantee of the possibility of termination of the entire grant and allow the grantee to withdraw its termination request. If the grantee does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire grant for cause.

See "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" in this subsection. The subject of debarment and suspension as an eligibility criterion is addressed in "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, which specifies the period of time for repayment, 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 (also see 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 also will 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 and accurate final reports may affect future funding to the organization or awards with the same PI.

Final Financial Status Report

A final FSR is required for:

- Any grant that is terminated.
- Any grant that is transferred to a new grantee.
- Awards, including awards under SNAP, which 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 indicate the exact balance of unobligated funds. Unobligated funds must be returned to NIH or must be reflected by an appropriate accounting adjustment in accordance with instructions from the GMO or from the payment office. For those organizations receiving their funds through PMS, final reports, as specified by PMS, must be submitted to that office. It is the 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.
- NIH must receive the revised FSR within 15 months of its due date.

Final Progress Report

The final progress report should include 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. The final progress report also should:

- Report on the inclusion of gender and minority study subjects (using the gender and minority inclusion table as provided in the PHS-2590).
- Where appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see "Public Policy Requirements and Objectives—Requirements for Inclusiveness in Research Design—Inclusion of Children as Subjects in Clinical Research" and the PHS-398).
- Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed.

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

Final Invention Statement and Certification

The grantee must submit a Final Invention Statement and Certification (HHS-568), whether or not an invention(s) results from work under the grant. The final invention statement/certification must be signed by the PI and an authorized organizational 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 those appeals that have been reviewed and acted on by NIH.

In addition to the adverse determinations indicated, the DAB is the single level of appeal for disputes related to the establishment of F&A cost rates, research patient care rates, and certain other cost allocations used in determining amounts to be reimbursed under NIH grants (e.g., cost allocation plans negotiated with State or local governments and computer, fringe benefit, and other negotiated special rates).[21]

[21] 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.

Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities

This subpart includes terms and conditions that vary from or are in addition to the standard requirements and terms and conditions in Subpart A of this Part because of the type of grant, grantee, or grant-supported activity.

The terms and conditions cited in this subpart may apply in addition to, or in lieu of, those in Subpart A. Each section of this subpart specifies how the coverage relates to that in Subpart A. Cross-references in this Part to other sections within this subpart specifically note this; otherwise the cross-reference is to the cited section in Subpart A.

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 non-construction grants);
- Individual and Institutional National Research Service Awards (NRSAs) (also termed "fellowships" and "training grants");
- Modular applications and awards;
- Conference grants;
- Consortium agreements;
- Grants to foreign institutions, international organizations and domestic grants with a foreign component;
- Grants to Federal institutions and payments to (or on behalf of) Federal employees under grants;
- Grants to for-profit organizations; and
- Research patient care activities.

CONSTRUCTION GRANTS

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

Except as indicated, for construction grants these requirements apply in lieu of the requirements in Subpart A of this Part. Applicants and grantees also should 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 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 Subpart A, construction grants are subject to the following public policy requirements. Questions about whether a particular requirement applies to A&R activities under non-construction grants should be directed to the GMO. Grantees receiving construction grants also must require contractors and subcontractors providing construction services to comply with certain Federal labor standards. These labor standards are discussed in "Equal Employment Opportunity, Labor Standards, and Other Contract Requirements" in this section.

The National Environmental Policy Act of 1969

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 non-construction projects as specified by NIH) 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.

If NEPA applies, the application for construction assistance must 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 indicates 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 must be received by (date). The Federal grant application may be reviewed at the Office of the Dean, School of Medicine, 5333 Main Street, during normal working hours."

Flood Insurance

The Flood Disaster Protection Act of 1973, as amended (Public Law 93-234), provides that no Federal financial assistance to acquire, modernize, or construct property may be provided in identified flood-prone communities in the 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 applies 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 the National Historic Preservation Act, as amended, and the Archeological and Historical Preservation Act of 1960, as amended, the Secretary of the Interior has compiled a National Register of Historic Places—sites and buildings of significant importance to U.S. history.[22] The statutes require that, prior to approval of a construction grant application (or applications for other grant-supported activities, as specified by NIH), NIH take into account the effect on these sites of the proposed construction (or other) project. The applicant must determine whether activities using NIH financial assistance will affect a property listed in the National Register. If a designated historic property 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 will delay NIH action on an application. The State Historic Preservation Liaison Officer or the National Trust for Historic Preservation may be contacted for additional details.

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[22] 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, telephone: (202) 606-8503. The National Trust for Historic Preservation is located at 1785 Massachusetts Avenue, NW, Washington, DC 20036, telephone: (202) 588-6000 or 1-800-944-6847.

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.whitehouse.gov/omb/grants/spoc.html 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 to NIH with the application, or the application must indicate the date on which the application was provided to the SPOC for review. If SPOC comments are not submitted with the application, the applicant must provide them upon receipt and may include its reaction to the comments, or 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 Relocation Act), 42 U.S.C. 4601 et seq., applies to all programs or projects undertaken by Federal agencies or with Federal financial assistance that cause the displacement of any person.

The HHS regulations and procedures for complying with the Uniform Relocation 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[23]

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. In addition, NIH will determine whether the final plans and specifications conform to the minimum standards of construction and equipment specified in 42 CFR Part 52b, in the *NIH Design Policy and Guidelines* issued by the Division of Engineering Services, NIH, and in the documents cited in this subsection. (The *NIH Design Policy and Guidelines* are available at http://des.od.nih.gov/eWeb/planning/html/nihpol.htm These standards are subject to modification by the Division of Engineering Services, NIH. The grantee will be subject to the standards in effect at the time of design or construction, as appropriate. NIH will monitor compliance during the project's design phase.

Where State or local codes are proposed 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 apply.

Elimination of Architectural Barriers to the Physically Handicapped

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

[23] 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.

services under the grant. Also see "Public Policy Requirements and Objectives—Civil Rights—Rehabilitation Act of 1973."

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 be 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, also are 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 Fossmoor 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, Birmingham, 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 also may 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, ISBN 0-309-05229-7; http://books.nap.edu/catalog/4911.html

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).

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 normally is not used for construction grants.

Matching

NIH construction grants generally require the grantee to share in the costs of the project. This requirement, if applicable, is stated as a matching percentage, 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 generally does not 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 major 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.
- Completion of unfinished shell space to make it suitable for purposes other than human occupancy, such as the storage of pharmaceuticals.
- Fixed equipment, such as casework, fume hoods, large autoclaves, or biological safety cabinets.

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

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

When the grantee's own construction and maintenance staff are used in carrying out the A&R (i.e., force account), the associated costs are allowable provided the grantee can document that force account is less expensive than if the project were competitively bid, and 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 a 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 shell space designed for completion at a future date.
- Consultant fees not related to actual construction.
- Damage judgment suits.
- Equipment purchased through a conditional sales contract.
- Fund-raising expenses.
- Land acquisition.
- Legal services not related to site acquisition.
- Movable equipment.
- Off-site improvements.

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.

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

Where more than one NIH or HHS program will support a construction project, or where the NIH-supported project is less than the entire facility or construction to be bid, the grantee must obtain bids that provide, to the maximum extent possible, the costs for that portion of the total job that will be financed by NIH funds and any required grantee matching. This may be done by (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 address both the technical qualifications of the offeror (possibly 75 percent of the evaluated score) and the business (cost) aspects of the proposal (possibly 25 percent of the evaluated score). The award 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 be procured by sealed bidding if 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) pre-qualify 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 must 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 will 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 applies whether or not phased construction techniques are employed. Each portion of the work for which a separate contract is expected to be let shall be separately priced as an individual line item in the GMP contract.

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

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

- 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 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 must 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 the RFP, provided that at least one form of the announcement receives nationwide distribution; consideration of all proposals from firms that are determined to be qualified; and selection based on the firms' qualifications, responsiveness to the criteria in the RFP, and cost.

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

- Technical considerations 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 grantee (owner) must ensure a firm total cost by including in the contract a provision that extra costs resulting from errors or omissions in the drawings or estimates will be the design-build firm's responsibility.

Equal Employment Opportunity, Labor Standards, and Other Contract Requirements

Labor standards and equal employment opportunity requirements for federally assisted construction must be specified in the information provided to bidders on construction contracts under NIH grants and must be included in the 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 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/dol/esa/public/ofcp_org.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 GMO when the account is closed.

Administrative Requirements

Prior Approval Requirements

Construction Grants

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

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

Real property constructed under an NIH grant-supported project is subject to the requirements of 42 CFR Part 52b and the provisions of 45 CFR 74.30 through 74.32 and 74.37 or 92.31, as applicable, regarding use, transfer of title, and disposition, unless alternate requirements are specified in the governing statute. For example, the governing statute for a construction grant program

may contain usage and disposition requirements that are in addition to or different from the usage and disposition requirements of 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, apply. Real property constructed or renovated with NIH grant support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the grantee, except as expressly authorized in writing by NIH. In the event of any default of any description under a mortgage on the part of a grantee, the grantee shall immediately provide the designated GMO with both telephonic and written notification of the default.

The mortgage agreement shall:

- Provide that the mortgagee notify NIH at least 30 days prior to initiating foreclosure action;
- Specifically allow, in the case of default, that NIH or its designee may assume the role of mortgagor and continue to make payments; and
- 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 (NIH) share of the property.

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

Use and Disposition

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 for the duration of the required use period. After the required usage period, the grantee has no further accountability to NIH concerning the use of the property or any sales proceeds.

For disposition of property acquired on an amortized acquisition basis, the formulas in 45 CFR 74.32 and 92.31 do not apply in determining the Federal share. In cases of amortized acquisition, the Federal share will be determined by multiplying the amount of mortgage principal already repaid at the time of disposition by the average Federal participation (taken from the 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 has undergone major renovation with NIH 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 type of insurance coverage as they maintain for other property they own, consistent with the minimum coverage specified below. "Completion of construction" means either the point at which the builder turns the facility over to the grantee (e.g., the date of the final acceptance of the building) or the date of beneficial occupancy, whichever comes first.

Federally owned property provided to a grantee for use need not be insured by the grantee. If title to real property acquired with NIH grant funds vests in the grantee, the following minimum insurance coverage is required:

- 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 active 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 organizational 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 NIH IC 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 organization's endowment or other special funds set aside specifically for this purpose.

EXHIBIT II-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 II-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 proposal
_____

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 Awards (NRSA) guidelines for individual and institutional awards. 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.

General

Background

Section 487 of the Public Health Service Act (PHS Act) (42 U.S.C. 288) provides authority for the National Institutes of Health (NIH) to award NRSAs to support predoctoral and postdoctoral training. This section of the PHS Act states that the Secretary shall provide NRSAs 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 NRSA 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 "Payback Reporting—Requirements for Recipients"). The regulations at 42 CFR Part 66 are applicable to these awards.

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 for Civil Rights, Office of the Secretary, DHHS before a grant may be made to that institution. The NIH IC should be contacted if there are any questions concerning compliance. (See "Public Policy Requirements and Objectives—Civil Rights.")

Individual National Research Service Awards (Fellowships)

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, NIH awards 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 Fellow-

ships (F33s) also are provided under the NRSA authority. For individual predoctoral fellowships, NIH awarding offices have differing requirements. Thus specific program announcements should be consulted for guidance.

NRSAs 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 NRSAs. FIC and NLM have unique funding authorities for fellowships that are not under the NRSA authority.

Eligibility

Research Areas

NRSAs may be made for research training in areas that fall within the mission of the NIH ICs. Applications that do not fit these areas will be returned. An increased emphasis has been placed on the research training of physicians. The 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 2 consecutive years of biomedical and behavioral research training.

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 be used 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 that are part of the research training.

Degree Requirements

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.

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 also is acceptable.

SENIOR FELLOWS

As of the beginning date of their award, senior fellows must have received a doctoral degree (as in "General—Degree Requirements—Postdoctoral") and must have had at least 7 subsequent years of relevant research and professional experience. The senior fellowship is awarded to provide opportunities for experienced scientists to make major changes in the direction of their research careers or to broaden their scientific backgrounds by acquiring new research capabilities. In addition, these awards will enable individuals beyond the new investigator stage to take time from regular professional responsibilities 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 that are part of their research training. More information on the Senior Fellowship program can be found in the NIH NRSA Senior Fellows (F33) Program Announcement published in the *NIH Guide for Grants and Contracts*.

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. Non-citizen nationals are persons, who, although not citizens of the United States, owe 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 6-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 check the same box, but should write in the word "pending."

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

Sponsorship

GENERAL

Before submitting a fellowship application, the applicant must identify a sponsoring institution and an individual who will serve as a sponsor and 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 doctoral institution or at the institution where they have been training for more than a year must document thoroughly the opportunity for new training experiences that would broaden their scientific backgrounds.

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.

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 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.)

Individuals on Active Military Duty

NIH does not restrict career military personnel from 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 allowances during the period of the requested fellowship. If an award is made, the institutional allowance and necessary tuition and fees permitted on a postdoctoral program will be paid by NIH. However, stipends, health insurance, and travel allowances are not allowable charges to the NRSA award for career military personnel. Payment of concurrent benefits by NIH to active duty career military awardees is not allowed.

Application Requirements and Receipt Dates

Application

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

Applicants and sponsoring institutions must comply with policies and procedures governing 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.

If an application is submitted in response to a Program Announcement (PA) or Request for Application (RFA) from a particular IC, the applicant should identify the number of the PA or RFA on the face page. This information will be used as a guide in the application assignment process.

Concurrent Applications

An individual may not have two or more competing NRSA applications pending review concurrently.

Application Availability

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

Division of Extramural Outreach and Information Resources, OER, NIH
Rockledge I, Suite 1120, MSC-7974
Bethesda, MD 20892-7974
Phone: (301)-435-0714
E-mail: GrantsInfo@nih.gov

Receipt Dates

Individual fellowship applications undergo a review process that takes between 5 and 8 months. The annual receipt dates and review cycle are found in Appendix II-1.

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 IC 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.

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 IC Program Official not the scientific review administrator of the SRG. A Notice of Research Fellowship Award will be issued to applicants selected for funding.

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 5 years of aggregate NRSA support at the predoctoral level and 3 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 NIH awarding office based on review of justification from the individual and sponsoring institution. The grounds for approving extensions of support are as follows:

Physicians/Clinicians

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

Interruptions (Break-In-Service)

Requests for additional time also will be considered if an event unavoidably 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 prevent a trainee or fellow from pursuing research training in an effective manner for a significant period of time. Requests for extension of support also will be considered if a short additional period would provide the

fellow an opportunity to use an exceptional training resource directly related to the approved research training program.

Other Exceptions

Requests that do not arise from circumstances covered in "Period of Support—Physicians/Clinicians or Interruptions (Break-in-Service)" 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 organizational official, must endorse the request certifying the need for additional support. The request must specify the amount of additional support for which approval is sought.

Initiation of Support

Process

The NIH IC 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 allows the individual to begin the fellowship immediately on or after the issue date, but permits a period of up to 6 months for the individual to finalize arrangements, such as the completion of degree requirements, final coordination with the sponsor, and, if necessary, a move to the sponsoring institution. The fellow must start the period of training under the award by the latest activation date as shown on the Notice of Research Fellowship Award, i.e., 6 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 must be countersigned by the sponsor and authorized organizational official.

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 NIH awarding office as of the day the fellow begins training (see "Reporting Procedures—Activation Notice" and "Reporting Procedures—Payback Agreement"). 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 to the NIH IC. 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 institution's business office, the sponsor, and the NIH IC immediately, in writing.

Payment

DOMESTIC

Domestic, Non-Federal

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

Federal Laboratories

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

FOREIGN

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

Financial Provisions

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

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.

LEVELS

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

Predoctoral

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

Postdoctoral

The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience 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.

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.

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 VA benefits when permitted by those programs as described in "Financial Provisions—Stipends—Educational Loans or G.I. Bill."

COMPENSATION

It is recognized that fellows may seek part-time employment coincidental to their training program in order to offset further their expenses. Funds characterized as compensation may be paid to fellows only when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions of the compensation of students as detailed in "Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages—Compensation of Students." Additionally, compensation must be in accordance with institutional policies applied consistently to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship agreement. Under these conditions, the funds provided as compensation (salary or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation, and are allowable charges to Federal grants, including PHS research grants. However, it is expected that compensation from research grants will be for limited part-time employment apart from the normal training activities.

Compensation may not be paid from a research grant that supports the same research that is part of the fellow's planned training experience as approved in the fellowship application. Under no circumstances may the conditions of stipend supplementation or the services provided for

compensation interfere with, detract from, or prolong the fellow's approved NRSA training program. 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.

Concurrent Benefits

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

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.

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, affects the tax liability of all individuals supported under the NRSA program. Degree candidates may exclude from gross income (for tax purposes) any amount used for course tuition and related expenses such as fees, books, supplies and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are 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, recipients of NRSA fellowships are not considered to be in an employee-employer relationship with the NIH or the sponsoring institution solely as a result of the NRSA award.

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

Form 1099

Although stipends are not considered salaries, this income is still subject to Federal and, sometimes, State income tax. Such income may be reported by the sponsoring institution on the IRS Form 1099, Statement of Miscellaneous Income. Normally, 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 (fellows at domestic non-Federal institutions). It should be noted, however, that sponsoring institutions are not required to issue a Form 1099, but it does serve as a useful form of documentation of income received and as a reminder to the fellow that some tax liability may exist. Fellows are reminded that, even if the sponsoring institution does not issue the Form 1099, they are still required to report NRSA stipends as income. NIH will is-

sue a Form 1099 for each fellow training at a Federal or foreign laboratory and receiving a stipend check from the U.S. Treasury.

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).

Other Costs

INSTITUTIONAL ALLOWANCE

NIH awards an institutional allowance to help support the costs of training. 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 II-2. Beginning in FY 1997, for postdoctoral fellowships, costs for tuition and fees, where appropriate, will be awarded independent of the institutional allowance. (See "Financial Provisions—Other Costs—Tuition and Fees" for details on tuition reimbursement.)

The institutional allowance is a fixed amount. Expenditures under institutional allowances are not subject to NIH prior approval requirements and the institution is not required to account for these expenditures on an actual cost basis. However, NIH policy governs the type of expenditures appropriate for the institutional allowance.

Allowable Costs for Sponsoring Institutions

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

Non-Federal public and private non-profit institutions (domestic and foreign)

The allowance is intended to defray 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.

Federal laboratories

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

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.

Guidelines

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

Health Insurance

A fellow's health insurance is an allowable cost only if applied consistently to all persons in a similar training status regardless of the source of support. Family health insurance is an allowable cost for fellows who have families and are eligible for family health insurance coverage at the sponsoring institution. Self-only health insurance is an allowable cost for fellows without families.

Travel

Payment for travel to scientific meetings is appropriate when it is necessary to the individual's training and when the costs are incurred within the period of grant-supported training.

For fellows at Federal laboratories, reimbursement of travel costs must be in accordance with current Government travel regulations.

Funds may not be expended to cover the costs of travel between the fellow's place of residence and the domestic training institution, except that the grantee institution may authorize the cost of a one-way travel allowance in an individual case of extreme hardship.

Extraordinary Costs

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

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 6 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 NIH IC authorizes the expenditure of the allowance. Payment is made through OFM.

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 NIH awarding office. For the purposes of calculating this budget item, health insurance is not included since it is part of the institutional allowance.

For predoctoral fellows, the award of tuition and fees (including health insurance) varies depending on the policy of the NIH awarding office. Specific programmatic guidelines should be consulted for guidance. Also see Appendix II-2.

When tuition, fees and insurance are awarded as a separate budget item, these funds may not be rebudgeted into any other budget category with written prior approval from the NIH IC.

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.

Reporting Procedures

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

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 (see Appendix II-3).

For fellows paid directly by NIH, the Activation Notice is required at the start of each award year. The form should not be submitted before the fellow actually begins training. Stipend checks are issued when both the Activation Notice and the Payback Agreement (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 IC immediately. Competing continuation awards must be activated on the day following the end of the last budget period of the previous award.

Payback Agreement

A National Research Service Award Payback Agreement (Form PHS 6031) that covers the initial 12 months of NRSA postdoctoral support must be signed by each person who is to receive an individual postdoctoral fellowship t. If the individual has already received 12 months of postdoctoral NRSA support under any training grant or fellowship award, this form is not required. No Payback Agreement is required for predoctoral fellows. For details on NRSA payback, see "Payback Reporting Requirements for Recipients."

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 validating the total period of NRSA support and establishing the amount of payback obligation for each NRSA fellow. For individual fellowships, a Termination Notice is sent to the fellow by the NIH 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 organizational official. This form must be completed and returned to the NIH IC immediately. The lack of timely and accurate information on this form could adversely affect the payback process.

Consecutive Support

If a fellow switches from one NRSA grant mechanism to another (e.g., from a training grant to a fellowship or from one NIH 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.

Progress Reports, Financial Status Reports, Changes in the Project

Progress Reports

Progress reports must be submitted with all applications for noncompeting 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.

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 6 months or less.

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. No activation notice is required from the new sponsoring institution.

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 NIH IC 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 3 months.

Other Terms and Conditions

Leave

VACATIONS AND HOLIDAYS

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

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 organizational official. Sick leave may be used for the medical conditions related to pregnancy and childbirth.

PARENTAL LEAVE

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

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 NIH IC. Fellows must provide a letter of support from the sponsor, countersigned by an authorized organizational official, and must advise the NIH IC of the dates of the leave of absence. Upon approval of the request, the NIH IC will issue a revised Notice of Research Fellowship Award extending the ending date of the current budget period by the number of months of the leave. A restriction is 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 by the sponsoring institution. When the fellowship is eventually terminated, the leave of absence must be clearly documented on the Termination Notice.

Termination

An individual NRSA may be terminated prior to its normal expiration date by 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. An award also may be terminated by NIH at the request of the recipient.

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. However, NIH IC support must be acknowledged by a footnote in language similar to the following: "This Investigation was supported by the National Institutes of Health, National Research Service Award (number) from the (name of NIH IC)." In addition, HHS funding must be acknowledged as provided in "Public Policy Requirements and Objectives—Availability of Information—Acknowledgment of Federal Funding."

Copyright

Except as otherwise provided in the conditions of the award, when publications or similar copyrightable materials are developed from work supported by NIH, the author is free to arrange for copyright without NIH IC approval. Any such copyrighted material shall be subject to a 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.

Patents

As specified in 45 CFR Part 74 and in 37 CFR 401.1(b), fellowships that are funded primarily for educational purposes, where the training will occur other than at NIH, are not subject to invention reporting requirements. Also, no fellowship made by NIH to an awardee primarily for educational purposes, where the training will occur other than at NIH, may 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.

Data Sharing

NIH policy is to make available to the public the results and accomplishments of the activities that it funds in a timely manner. Therefore, it is incumbent on fellows to make the results and accomplishments of their fellowship activities available to the public. The sponsoring institution should place no restrictions on the publication of results that conflicts with this policy.

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 program income (see "Administrative Requirements—Management Systems and Procedures—Program Income"). The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations. If permitted by organizational policy, these fees may be retained by the awardee.

Human Subjects/Animal Welfare/Recombinant DNA Molecules

HUMAN SUBJECTS

Individual NRSA awards involving use of human subjects must comply with the requirements for their protection (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects." For additional information on human subjects requirements, refer to the Individual NRSA application kit or contact OHRP (see contact information in Part III).

VERTEBRATE ANIMALS

Individual NRSA awards involving use of vertebrate animals must comply with the requirements for their protection (see "Public Policy Requirements and Objectives—Animal Welfare." For additional information on vertebrate animals, refer to the Individual NRSA application kit or contact OLAW (see contact information in Part III).

RECOMBINANT DNA MOLECULES

Individual NRSA awards involving use of recombinant DNA molecules must comply with the requirements of the *NIH Guidelines for Research Involving DNA Molecules* (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Recombinant DNA Molecules." The Guidelines, available from the Office of Biotechnology Activities (see Part III), should be consulted for complete requirements for the conduct of projects involving recombinant DNA techniques.

Institutional National Research Service Awards (Training Grants)

General

The National Institutes of Health (NIH) will award National Research Service Award (NRSA) Institutional Training Grants (T32s, T34s, and 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. All NIH awarding offices except the Fogarty International Center (FIC) and the National Library of Medicine (NLM) make Institutional NRSAs. FIC and NLM have unique funding authorities for training grants that are separate from the NRSA authority.

Eligibility

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 consulted for IC guidelines.) Support for short-term training positions for students in health-professional degree programs also may be requested as indicated in "Degree Requirements—Short-Term Research Training." Each applicant institution must submit an application according to instructions, using the appropriate forms (see "Application Requirements and Receipt Dates").

RESEARCH AREAS

Institutional NRSAs may be made for research training in areas that fall within the mission of the NIH ICs. Applications that do not fit these areas will be returned. An increased emphasis has been placed on the research training of physicians. The 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 2 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 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 primary objective of developing or extending their research skills and knowledge in preparation for a research career.

RESEARCH TRAINING PROGRAM

The Institutional NRSA 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 be used 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 that are part of the research training.

Degree Requirements

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, also may be appointed to a T32 grant. Predoctoral research training must emphasize fundamental training in areas of basic biomedical and behavioral sciences.

POSTDOCTORAL TRAINING

Postdoctoral research training is for individuals who have received a Ph.D., 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.

Students in Health Professional Schools

NIH offers two short-term training programs: those that are part of a traditional institutional training grant (T32) and those that exclusively support short-term trainees (T35). These short-term research training experiences of 2 to 3 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*.

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 ICs support short-term research training positions on a limited basis, applicants are strongly urged to contact the appropriate NIH IC before requesting short-term research training positions as part of a T32 application.

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 for the T32. 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.

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 that the applicant institution sets for itself. 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 4-year college or university) must propose a 2-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
6001 Executive Blvd.
Suite 8125
MSC-9659
Bethesda, MD 20814-9659(301) 443-3725

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. Non-citizen nationals are persons, who, although not citizens of the United States, owe 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 6-month limitation on this validation, it is the grantee's responsibility to follow-up and assure that the individual received the I-551 prior to the 6-month expiration date.

A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment Form (PHS Form 2271). Individuals on temporary or student visas are not eligible for NRSA support.

Application Requirements and Receipt Dates

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:

Division of Extramural Outreach and Information Resources, OER, NIH
Rockledge 1
Suite 1120
6705 Rockledge Drive, MSC-7974
Bethesda, MD 20892-7974
Phone: (301)-435-0714
E-mail: GrantsInfo@nih.gov

Receipt Dates

Some NIH ICs receive training grant applications three times each year; however, most ICs have one receipt date only. Information on receipt dates is available in the NIH-wide T32 Program Announcement published in *the NIH Guide for Grants and Contracts* or in RFAs issued by the individual NIH ICs. See Appendix II-1 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.

Review

Overall

Each initial and competing continuation application will be evaluated for scientific merit by a NIH peer review group. Institutional applications also must 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 2 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., or D.D.S. degree) with basic science postdoctorates (e.g., individuals with a Ph.D. or Sc.D.) or linkages with basic science departments will receive special consideration.

Applicants also are encouraged to consult the PHS 398 application kit, the NIH T32 Program Announcement and/or specific IC program announcements for additional details.

Short-Term Research Training Positions

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

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.

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 or postdoctorates who applied for admission or positions within the department(s) relative to the research training grant;
- Students or postdoctorates who were offered admission to or a position within the department(s);
- Students actually enrolled in the academic program relevant to the research training grant; and
- Students or postdoctorates that 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 competitive segment. The review group 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 competitive segment.

The findings of the review group will be included in an administrative note in the summary statement. If the minority recruitment plan of the application is judged to be unacceptable, funding will be withheld until a revised plan that addresses the deficiencies is received. Staff within the NIH IC, with guidance from 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 competitive segment also must be provided in progress reports included in all noncompeting applications.

Training in the Responsible Conduct of Research

All competing Institutional NRSA (training grant) applications must include a description of the formal and informal activities related to instruction in the responsible conduct of research that will be incorporated into the proposed research training program.

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

- Although NIH does not establish specific curricula or formal requirements, all programs are 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 research integrity, it also is beneficial to discuss the mutual responsibilities of the institution and the trainees participating in the program.

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

- 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 IC.

Following initial review, applications undergo a second level review by the appropriate NIH institute or center council, board, or other advisory group. In addition to the assessment of the scientific and educational merit of the research training grant application, these advisory groups will consider the initial review group's comments on the plan for instruction in the responsible conduct of research.

Information on the nature of the instruction in the responsible conduct of science and the extent of trainee and faculty participation also must be provided in progress reports included in all noncompeting applications.

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 IC. The IC 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 recommendation. 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 Program Official not to the scientific review administrator of the SRG.

Period of Support

Institutional Grants

Grants may be made for competitive segments of up to 5 years and are renewable. Awards within an approved competitive segment are normally made in 12-month increments with support for additional noncompetitive years dependent upon satisfactory progress and availability of funds.

Trainees

Trainees customarily are appointed for full-time 12-month continuous periods. An appointment or reappointment may not exceed 12 months without prior approval by the NIH awarding office. All trainees are required to pursue their research training 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 ob-

ligated by the grantee 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 NRSA for a period of less than 9 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 9 months may be allowed as long as an assurance is included that the individual will be immediately reappointed in the subsequent year so that the cumulative continuous training period is at least 9 months.

NRSA Limitations

No individual trainee may receive more than 5 years of aggregate NRSA support at the predoctoral level and 3 years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional and individual NRSAs. Any exception to this requires a waiver from the IC based on review of a justification from the individual and grantee organization. The grounds for approving extensions of support are as follows:

PHYSICIANS/CLINICIANS

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

INTERRUPTIONS (BREAK-IN-SERVICE)

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

OTHER EXCEPTIONS

Requests that do not arise from circumstances covered in "Period of Support—NRSA Limitations—Physicians/Clinicians" or in "Period of Support—NRSA Limitations—Interruptions (Break-in-Service)" will be considered if they are accompanied by an exceptionally strong justification. Requests must be made in writing to the NIH IC by the trainee. The trainee's program director and an authorized organizational official must endorse the request certifying the need for additional support. The request must specify the amount of additional support for which approval is sought.

Initiation of Support

A Notice of Grant Award is issued to the grantee organization, normally for 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 NIH IC.

At the time of the initial appointment and subsequent reappointment, the training program director **must** submit a Statement of Appointment Form to the NIH IC. 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 "Reporting Procedures—Statement of Appointment (Form PHS-2271)" and "Reporting Procedures—Payback Agreement (Form PHS-6031)" 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 organization directly to the trainee.

Financial Provisions

Stipends

A stipend is provided as a subsistence allowance 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 organization. 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 organization with the trainee For appointments of less than 12 months, the stipend will be prorated.

LEVELS

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

Prebaccalaureate

Two separate levels are provided for trainees: Freshman/Sophomore or Junior/Senior.

Predoctoral

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

Postdoctoral

The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience at the time of appointment Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the trainee must be paid at that level for

the entire period of appointment. The stipend for each additional year of NRSA support is the next level in the stipend structure and does not change mid-year.

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 formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar training status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. An individual may make use of Federal educational loan funds or VA benefits when permitted by those programs as described in "Financial Provisions—Stipends—Educational Loans or G. I. Bill." Under no circumstances may PHS funds be used for supplementation.

Student Compensation

It is recognized that trainees as students may seek part-time employment coincidental to their training program in order to offset their expenses further Funds characterized as compensation may be paid to trainees only when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions of the compensation of students as detailed in "Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages—Compensation of Students." Additionally, compensation must be in accordance with organizational policies applied consistently to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation (salary or tuition remission) for services rendered, such as teaching or laboratory assistance are not considered stipend supplementation, and are allowable charges to Federal grants, including PHS research grants. However, it is expected that compensation from research grants will be for limited part-time employment apart from the normal full-time training activities

Compensation may not be paid from a research grant that supports the same research that is part of the trainee's planned training experience as approved in the training grant application.

Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the trainee's approved NRSA training program. 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.

Concurrent Benefits

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

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.

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, affects the tax liability of all individuals supported under the NRSA program Degree candidates may exclude from gross income (for tax purposes) any amount used for course tuition and related expenses such as fees, books, supplies and equipment required for courses of instruction at a qualified educational organization Non-degree candidates are required to report as gross income all stipends and any monies paid on their behalf for course tuition and fees required for attendance.

However, the taxability of stipends in no way alters the relationship between NRSA trainees and organizations NRSA stipends are not considered salaries. In addition, trainees supported under NRSAs are not considered to be in an employee-employer relationship with the NIH or the grantee organization solely as a result of the NRSA support

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

FORM 1099

Although stipends are not considered salaries, the income is still subject to Federal and, sometimes, State taxes Such income may be reported by the grantee organization on the IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the grantee organization will be responsible for the annual preparation and issuance of the IRS Form 1099 for trainees. It should be noted, however, that grantee organizations are not required to issue the Form 1099, but it does serve as a useful form of documentation of income received and as a reminder to the trainee that some tax liability may exist. Trainees are reminded that, even if the grantee organization does not issue the Form 1099, they are still required to report NRSA stipends as income.

EMPLOYEE BENEFITS

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

Other Direct Costs

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 II-2. Interested applicants should 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 level. 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.

TRAINEE TUITION AND FEES

Tuition, fees, and health insurance (self-only or family) are allowable trainee costs only if such charges are applied consistently to all persons in a similar training status at the organization, without regard to their source of support Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program and requires prior approval of the NIH IC. 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 II-2.

TRAINEE TRAVEL COSTS

If requested by the organization, the NIH IC may award grant funds to cover the costs of trainee travel, including attendance at scientific meetings, that the organization determines is necessary to the individual's training. Funds may not be expended to cover the costs of travel between the trainee's place of residence and the training institution, except that the grantee organization may authorize a one-way travel allowance in an individual case of extreme hardship.

In addition, support for travel to a research training experience away from the grantee organization may be permitted. Research training experiences away from the parent organization must be justified considering the type of opportunities for training available, how these opportunities differ from those offered at the parent organization, and the relationship of the proposed experience to the trainee's career stage and career goals This type of research training requires prior approval from the NIH IC. Letters requesting such training may be submitted to the NIH awarding office at any time during the appointment period.

SHORT-TERM

The grantee 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.

Rebudgeting of Funds

TRAINEE-RELATED EXPENSES

Rebudgeting of funds awarded in lump sum for trainee-related expenses does not require NIH IC prior approval.

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 NIH IC. Unless otherwise restricted, rebudgeting into or within the stipends and tuition/fees categories is allowable without awarding office prior approval.

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 NIH IC prior approval

Expenditure of Funds

Policies included in the applicable cost principles and in this policy statement govern the expenditure of all training grant funds, unless otherwise indicated in the Notice of Grant Award.

Facilities and Administrative (F&A) Costs

The organization, other than a State, local or Indian tribal government, will receive F&A costs (previously "indirect costs") at 8 percent of modified total direct costs (exclusive of tuition and fees, health insurance, and expenditures for equipment) rather than on the basis of a negotiated rate agreement. Applications from State and local government agencies, except State universities or hospitals, may receive full F&A cost reimbursement.

Program Income

Applicants for NIH research grants, including training grants, are required to include in their grant applications an estimate of the amount and source of program income expected to be generated as a result of the project for which support is being sought. See "Administrative Requirements—Management Systems and Procedures—Program Income" for policies that govern the treatment of program income.

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

Statement of Appointment (Form PHS 2271)

GRANTEE SUBMISSION

The grantee 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 also must 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 organizational financial officials should coordinate the information reported on the Statement of Appointment. It should be treated as a financial document for obligating funds (stipends), which later are reflected on the Termination Notice and as part of the total costs in the Financial Status Report. A supply of Statement of Appointment Forms (PHS 2271) is provided to the program director by the NIH IC.

INTERIM REVISIONS

Any changes or corrections involving a trainee appointment under an institutional grant, such as name, permanent mailing address, period of training, or 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.

Payback Agreement (Form PHS 6031)

A National Research Service Award Payback Agreement that covers the initial 12 months of NRSA postdoctoral support must be signed by each postdoctoral individual. If the individual has already received 12 months of postdoctoral support under any NRSA training grant or fellowship award, this form is not required. No Payback Agreement is required for predoctoral or prebaccalaureate trainees. For details on NRSA payback, see "Payback Reporting Requirements for Recipients."

Termination Notice (Form PHS 416-7)

The Termination Notice is the basis (along with the Statement of Appointment Form) for validating the total period of NRSA support and establishing the amount of payback obligation (if any) for each NRSA trainee. For an institutional award, the NIH IC 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. The lack of timely and accurate information on this form could adversely affect the payback process.

Consecutive Support

If a trainee switches from one NRSA grant mechanism to another (e g., from an individual fellowship to a training grant) or from one NIH awarding office to another, the requirement for

payback service incurred is deferred until the total NRSA support is completed. All Statement of Appointment forms are reviewed to determine if previous NRSA support has been provided.

Progress Reports, Financial Status Reports, and Changes in the Project

Progress Reports

Progress reports must be submitted with all applications for noncompeting 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, if continued funding is not being provided, a final progress report must be submitted to the NIH awarding office within 90 days after the end of the final budget period of the project period.

Financial Status Report (FSR)

An annual 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 organization Trainee stipends and tuition are obligated for the full 12-month appointment from the budget period in which the appointment is initiated. Portions of stipends and tuition that extend beyond the budget period are carried over as unliquidated obligations. However, if the report covers the final budget period of the project period, it must have no unliquidated obligations and must indicate the exact balance of unobligated funds.

Changes in the Project

Changes in the program objectives as they relate to the area of research training for which the grant was approved require prior approval from the NIH IC

Where absence of the program director is expected to exceed a continuous period of more than 3 months, plans for the conduct of the program during his or her absence must be approved in writing by the NIH IC. Any proposed change of program director must be requested by the grantee organization 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

Institutional NRSAs may not be transferred from one domestic organization to another except under the most unusual circumstances Such a change will generally be approved by the NIH IC only if all of the major benefits attributable to the original grant can be transferred and there is no negative impact on trainees active in the program.

Other Terms and Conditions

Leave

VACATIONS AND HOLIDAYS

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

Sick Leave and Other Leave

Trainees may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH IC in response to a written request from the training program director countersigned by an authorized organizational official. Sick leave may be used for the medical conditions related to pregnancy and childbirth.

Parental Leave

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

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

Unpaid Leave

Individuals requiring extended periods of time away from their research training experience, 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 NIH IC 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 organizational 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 NIH IC at the beginning of the leave. At the resumption of NRSA support, the reappointment must be documented on another Statement of Appointment Form.

Termination

An institutional NRSA may be terminated prior to its normal expiration date by 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 IC shall notify the awardee in writing of this determination, the reasons therefore, the effective date, and the right to appeal the decision. An award also may be terminated by NIH at the request of the recipient.

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, NIH IC support must be acknowledged by a footnote in language similar to the following: "This in-

vestigation was supported by National Institutes of Health, National Research Service Award (number) from the (name of NIH IC)." In addition, HHS funding must be acknowledged as provided in "Public Policy Requirements and Objectives—Availability of Information—Acknowledgment of Federal Funding."

Copyright

Except as otherwise provided in the conditions of the award, when publications or similar copyrightable materials are developed from work supported by NIH, the author is free to arrange for copyright without NIH IC approval Any such copyrighted material shall be subject to a 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

Patents

As specified in 45 CFR Part 74 and in 37 CFR 401.1(b), training grants funded by NIH are not subject to invention reporting requirements. NIH has no rights to any inventions or any income resulting from inventions conceived or first actually reduced to practice during the course of a training grant.

Data Sharing

NIH policy is to make available to the public the results and accomplishments of the activities that it funds in a timely manner. Therefore, it is incumbent upon the program directors and trainees to make the results and accomplishments of their NRSA institutional training grant activities available to the public. The grantee organization should place no restrictions on the publication of results that would conflict with this policy.

Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award may not be retained by the trainee. Such fees will be assigned to the grantee organization for disposition in accordance with NIH policy on program income (see "Administrative Requirements—Management Systems and Procedures—Program Income"). The term professional fees does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations. If permitted by organizational policy, these fees may be retained by the awardee.

Human Subjects/Animal Welfare/Recombinant DNA Molecules

HUMAN SUBJECTS

Institutional NRSAs involving use of human subjects must comply with the requirements for their protection (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects." If the applicant organization has an approved Assurance of Compliance on file

with Office for Human Research Protections (OHRP) 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 applicant 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 NRSAs will be participating in research supported by research project grants for which the IRB review is already completed or an exemption is already designated. This review or exemption designation is sufficient, provided the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation.

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

Vertebrate Animals

Institutional NRSAs involving use of vertebrate animals must comply with the requirements for their protection (see "Public Policy Requirements and Objectives—Animal Welfare").

If the applicant organization has an approved Assurance of Compliance on file with OLAW but, at the time of application, 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 applicant 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 IC.

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, provided the research would not be substantially modified by the participation of a trainee The appropriate grants must be identified along with their IACUC review dates

For additional information on vertebrate animals, refer to the PHS-398 or contact OLAW (see Part III).

Recombinant DNA Molecules

Institutional NRSAs involving use of recombinant DNA molecules must comply with the requirements of the *NIH Guidelines for Research Involving DNA Molecules* (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Recombinant DNA Molecules." The Guidelines, available from the Office of Biotechnology Activities, NIH (see Part III), should be consulted for complete requirements for the conduct of projects involving recombinant DNA techniques.

Payback Reporting Requirements for Recipients

General

The 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 "Payback—Service Payback—Definitions" for a complete interpretation

The National Institutes of Health 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.

Implementation

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

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

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 receive the allowance (this was retroactive to the beginning of the NRSA program). Individuals in delinquent status continued to have a payback obligation for all support received. This legislative change also eliminated the payback obligation for prebaccalaureate recipients

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

Effective June 10, 1993 (NIH Revitalization Act)

PREDOCTORAL RECIPIENTS

For **predoctoral** trainees beginning appointments and for **predoctoral** fellows activating awards on or after June 10, 1993, no payback obligation is incurred. Thus a Payback Agreement Form (PHS 6031) is no longer required

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 "Payback—Service Payback—Initiation of Payback Service" for detailed changes effective with the Act.

SHORT-TERM TRAINING

Any predoctoral short-term training does not incur a payback obligation. Postdoctoral short-term training incurs a payback obligation. Any support accrues along with any subsequent postdoctoral support until the first 12 months is established. At that point, the 13th and subsequent months of support serve to offset the obligation on a month-by-month basis. In the event that subsequent postdoctoral support is not received, the individual has an obligation to pay back in the traditional manner.

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, the Payback Service Center personnel are NIH's experts in the NRSA payback arena. For those awarding offices participating in the Center, the authorities normally delegated to the IC are automatically delegated to the Chief, NRSA Payback Service Center.

Most NRSA recipients eventually fulfill their payback obligation by engaging in activities that are determined to be acceptable service Some recipients fulfill their obligation via financial payback. On rare occasions waivers of the payback obligation are granted.

As indicated in "Payback Reporting Requirements for Recipients—Implementation," the amount of a payback obligation incurred is solely dependent upon when NRSA support was received. Timing of NRSA support also is a factor with respect to the type of service that qualifies as acceptable payback.

Service Payback

DEFINITIONS

For the purpose of fulfilling the NRSA service payback obligation, the following definitions apply:

Research

Research is defined as an activity that 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 that includes providing scientific direction and guidance to research may be acceptable if a doctoral degree and relevant research experience is required for individuals filling such positions. Such research can be conducted in an academic, government, commercial, or other environment in either a foreign or domestic setting.

In addition, when consistent with the cumulative amount, type, and frequency of research or research training experiences, functions that involve analytic or other technical activities conducted in direct support of research, as defined above, also will satisfy the service payback obligation.

Teaching

Teaching is an instructional activity that takes place in an organized educational or other instructional environment. Activities classified as teaching are generally carried out in a formal didactic setting but other activities will be considered if they are consistent with the certifying institution's policy on the definition of teaching responsibilities. Such teaching can be conducted at universities, professional schools, research institutes, teaching hospitals, primary schools, secondary schools, or colleges. When calculating hours of teaching per week, it is permissible to include 3 hours of preparation time for each hour of direct instruction. Acceptable teaching activities must have a biomedical or health-related relevance

Health-Related

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 also will be considered health-related.

TIME COMMITMENT

All acceptable activities must be undertaken for periods that average at least 20 hours per week Total employment in such activities averaging less than 20 hours per week cannot be counted 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 NIH IC.

Initiation of Payback Service

Support Received Prior to NIH Revitalization Act

For NRSA recipients who incurred a payback obligation from support received prior to 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 of NRSA support if the research or teaching activities meet the criteria cited in "Payback Reporting Requirements for Recipients—Payback—Definitions "

Support Received Post-NIH Revitalization Act

Beginning with awards made under the authority of the NIH Revitalization Act (appointments on or after June 10, 1993), service payback obligations for postdoctoral recipients may be discharged in the following ways:

- By receiving an equal number of months of postdoctoral NRSA support beginning in the 13th month of such postdoctoral NRSA support;
- By engaging in an equal number of months of health-related research, training and/or teaching averaging more than 20 hours per week.
- 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 that also satisfies **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.
- 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.

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 funds. An individual could be supported by a PHS grant or from any non-NRSA Federal or non-Federal source Unpaid service also is permitted.

TIMING OF SERVICE OBLIGATION

An individual must begin to undertake the payback service requirement within 2 years after the termination date of the individual's NRSA support unless an extension of time to begin payback has been approved by the NIH IC (see "Payback—Extensions of Payback—Extensions of the 2-Year Period to Initiate Payback").

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 NIH IC

Financial Payback

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:

$$A = O \frac{(t-s)}{(t)}$$

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.

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 2-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 3-year repayment period. If financial payback is involuntary, the date which determines the interest rate and the 3-year repayment period is the date of expiration of the 2-year period following the termination of NRSA support. For example, if during June 1998, OFM received an account reflecting January 31, 1996 as the termination date of NRSA support, the Government, lacking any documentation to the contrary, becomes entitled to financial payback effective February 1, 1998. The rate of interest applicable is determined based on the February 1, 1998 date and the total NRSA obligation is required to be fulfilled by January 31, 2001

The amount to be recovered financially, as determined from the Termination Notice plus applicable interest, shall be paid to the United States within the 3-year period following such date.

Extensions of Payback

The NRSA legislation and the implementing regulation (42 CFR Part 66) exceptions to certain requirements under the Act.

Extensions of the 2 Year Period to Initiate Payback

Frequently, an Annual Payback Activities Certification (APAC) (Form PHS 6031-1) is returned requesting an extension of the 2-year period to initiate payback. Indication of valid plans to initiate payback soon after the 2-year grace period may be good reason to grant an extension.

Basis for Extensions

The NIH IC may extend the period for undertaking payback service or permit breaks in continuous service. These determinations are based on the following criteria:

- an extension or break in service is necessary so the individual may complete his or her research or clinical training;
- the individual is unable to complete the requirements within the specified period because of a temporary disability; or
- 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 APAC) to the NIH IC, specifying the need for additional time and the length of the required extension.

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 "Payback—Extensions of Payback—Basis for Extensions "

Waiver

POLICY

The NRSA legislation and the implementing regulation (42 CFR Part 66) exceptions to certain requirements under the Act For waiver requests, NIH may waive, in whole or in part, the pay-back 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.

WAIVER CRITERIA

Requests for waivers should be made in writing to the NIH IC and explain the need for the waiver according to the following criteria.

- Compliance by an individual will be deemed impossible if the individual is permanently and totally disabled;
- In determining whether compliance would involve substantial hardship to the individual and would be against equity, the IC shall take into consideration:
  - the individual's financial resources and obligations at the time of request for a waiver;
  - the individual's estimated future financial resources and obligations;
  - In rare cases, the following also might be considered:
    - the reasons for the individual's failure to complete the requirements within the prescribed period, such as problems of a personal nature;
    - the extent to which the individual has engaged in payback activities;
    - whether the individual has received sufficient training to be qualified to perform such activities;
    - the lack of employment opportunities appropriate to the individual's education and training; and
    - any other extenuating circumstances.

Any obligation of any individual toward payback will be canceled upon death of the individual.

Certification of Payback Activities

Annual Payback Activities Certification (Form PHS 6031-1)

ANNUAL CERTIFICATION

Payback service is certified through the use of the 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 NIH IC, which 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.

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. Notification of changes can be made by letter, telephone, fax, or e-mail.

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 6 months or longer, the individual receives an APAC form through the regular mechanism. However, if the break is less than 6 months, an APAC will not be automatically mailed. If acceptable payback service was per-

formed during the break, the individual may complete an APAC, which can be obtained from the NIH IC, to document the payback service

National Health Service Corps

Occasionally, an NRSA recipient may have 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 that qualify as NRSA payback 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 NIH IC monitors both obligations until they are both satisfactorily completed

APPENDIX II-1
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

The ICs review T32 applications either once or three times per year. A listing of the ICs, specifying the receipt date(s) associated with their application review, is provided below.

Institute/Center	Application Receipt Date(s)
NCCAM	Jan 10, May 10, Sept 10
NCI	Jan 10, May 10, Sept 10
NCRR	Jan 10, May 10, Sept 10
NIA	May 10
NIAAA	May 10
NIAID	Sept 10
NIAMS	May 10
NICHD	May 10
NIDA	May 10
NIDCD	May 10
NIDCR	Sept 10
NIDDK	Jan 10, May 10, Sept 10
NEI	May 10
NIEHS	May 10

NHLBI	May 10
NHGRI	May 10
NIGMS (postdoctoral training grants)	Jan 10
NIGMS (predoctoral training grants)	Jan 10, May 10, Sept 10
NIMH (except Office of AIDS with three dates)	May 10
NINDS	May 10
NINR	May 10

Applicants are encouraged to confirm the application receipt dates by calling the appropriate IC Review Office Specific NRSA programs may change their receipt dates to complement IC workloads

APPENDIX II-2
NRSA FINANCIAL PROVISIONS

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

STIPENDS

Annual stipend levels apply to all individuals receiving support through institutional or individual NRSAs. Stipend levels 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.

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 $2,000 per year for each predoctoral trainee, and up to $3,000 per year for each postdoctoral trainee. The training-related expenses for specialized programs, such as MARC and COR, are referenced in the specific program announcements.

INSTITUTIONAL ALLOWANCE—Individual Fellowships

Provided annually to help defray the costs for the individual fellow. "Individual NRSAs (Fellowships)—Financial Provisions—Other Costs—Institutional Allowance" describes in detail what are considered acceptable costs for sponsoring institutions for individual fellowships depending on the training site. The institutional allowance is a fixed amount. Expenditures under institutional allowances are not subject to NIH prior approval requirements (as specified in Subpart A of this Part), and the organization is not required to account for these expenditures on an actual cost basis. However, NIH policy governs the type of expenditures appropriate for the institutional allowance.

Beginning with awards made with FY 2001 funds, whether competing or noncompeting, and until the allowance level is changed, an institutional allowance will be provided for each year of the fellowship as follows:

Predoctoral

Up to $4,000[24]. Note, many ICs provide individual predoctoral fellowships with a reduced institutional allowance (usually $2, 500) since costs for tuition, fees and health insurance are awarded separately. Specific program announcements and/or ICs should be contacted for guidance.

Postdoctoral

$5,000 per 12-month period (for fellows at non-Federal, non-profit, or foreign institutions).

Up to $4,000[25] (for fellows at Federal laboratories or for-profit institutions).

For postdoctoral fellowships, tuition and fees (except health insurance), when applicable, are no longer included as part of the institutional allowance. That cost is awarded in accordance with the tuition policy described below. The cost of health insurance is a charge to the institutional allowance.

TUITION AND FEES

Reference: *NIH Guide for Grants and Contracts*, Vol. 28, No. 51, December 23, 1999

In FY96, NIH instituted a new policy for funding tuition costs. **Note, applicant institutions are instructed to continue to request the full amount of these costs in competing applications. NIH IC staff will apply the formula at the time an award is calculated.** The formula is used for award calculation only. Actual reimbursement is not limited to the formula. Funds are awarded in a sum. Unless otherwise restricted, grantees may apportion funds as best meets their actual needs for tuition and fees.

Institutional Grants

For competing and noncompeting awards issued in FY 00 and until changed by NIH, the combined costs of tuition, fees and health insurance are funded at the following per trainee rate: 100% of all costs up to $3,000 and 60% of costs above $3,000. Future years provide no escalation.

Individual Postdoctoral Fellowships

For competing and noncompeting awards issued in FY 00 and until changed by NIH, when applicable, tuition and fees (excluding health insurance) are funded at the following rate: 100% of all costs up to $3,000 and 60% of costs above $3,000. Future years provide no escalation. For postdoctoral fellowships, health insurance will continue to be paid as part of the institutional allowance.

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[24] This change was effective at the beginning of FY 1997 for new, competing fellowships.

[25] This change was effective at the beginning of FY 1997 for new, competing fellowships.

Individual Predoctoral Fellowships

Payment of tuition and fees (including health insurance) varies among the NIH ICs. Therefore, specific program announcements and/or awarding offices should be contacted for guidance.

- When tuition and fees and health insurance are awarded as a separate cost, (for competing awards issued in FY97 and until changed by NIH), this cost will be funded at the following rate: 100% of all costs up to $3,000 and 60% of costs above $3,000. Future years provide no escalation.

- Non-competing awards funded in FY97 will continue to be reimbursed at previously established levels.

SHORT-TERM TRAINING—Students in Health Professional School

Most short-term trainees are funded at the predoctoral stipend level prorated for the number of months of support. 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, and travel. Some NIH ICs provide short-term training at the postdoctoral level as well. Specific program announcements and ICs should be contacted for guidance.

APPENDIX II-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 office.

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 office.

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 office.

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 office.

NRSA Annual Payback Activities Certifications (PHS 6031-1) are automatically mailed annually to applicable recipients.

These forms are available from the NIH Forms and Applications Page (http://grants.nih.gov/grants/forms.htm) located on the NIH Office of Extramural Research Administration's web site (http://grants.nih.gov/grants/oer.htm).

MODULAR APPLICATIONS AND AWARDS

General

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

Applicability

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

Instructions for specific grant mechanisms other than the R01 and guidelines for IC programs may indicate a particular number or range of modules allowed. In addition, an IC may, at its discretion, specify in an RFA that the modular application requirements apply to applications for amounts in excess of the modular ceiling (currently $250,000).

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

Application Requirements

Except as indicated in this subsection, the following instructions apply to use of the PHS-398. Instructions for modular submission under the SBIR/STTR programs are included in those solicitations.

Budget

Modular applications request direct cost funding in modules of $25,000, up to a maximum of $250,000, for each year of support. Total costs requested are comprised of modular direct costs plus applicable F&A costs. Standard application budget forms are not used. Instead, total direct costs requested for each year should be presented.

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

As appropriate, the narrative also must address consortium/contractual costs (including applicable F&A costs) rounded to the nearest $1,000. The narrative should list the individuals/organizations with whom consortium or contractual arrangements have been (or will be) made, the percent of effort of key personnel and their role on the project, and indicate whether the collaborating organization is foreign or domestic. If a contract/consortium arrangement is proposed, a letter of commitment or intent should be included. Sample modular application budget pages are available at http://grants.nih.gov/grants/funding/modular/modular.htm.

A typical modular application will request the same number of modules for each year; however, well-justified modular increments (up to the specified modular ceiling) or decrements in the total direct costs for any year of the project that reflect substantial changes in expected future activities may be requested at the outset. For example, purchase of major equipment in the first year may justify a higher overall budget in that year, but not necessarily in succeeding years. There is no provision for escalation in future years. NIH requires additional narrative budget justification if there is a variation in the number of modules requested from year to year.

Biographical Sketch

The "Other Support" pages of the PHS-398 are not submitted with the application. Information on other research activities of the PI and key personnel will be provided as part of the "Biographical Sketch." This information must include the specific aims of ongoing research projects or research projects completed during the previous 3 years. A biographical sketch is required for the PI and for all key personnel. The Biographical Sketch is limited to three pages per person. A sample biographical sketch is available at
http://grants.nih.gov/grants/funding/modular/modular.htm

Checklist

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

Non-compliant Applications

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

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

- The requested direct cost budget is not in modules of $25,000 for all years of support for requests up to $250,000 (total direct costs) per year.
- A detailed itemized categorical budget is provided.
- The budget narrative justification includes an itemized justification for one or more of the following: equipment, travel, supplies, other expenses, etc., but the number of modules re-

quested for each year is the same, or the information is not intended to explain the request for a different number of modules for one or more years.

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

Evaluation and Award

Scientific Review Groups (SRGs) evaluate the budget on the basis of a general, expert estimate of the total effort and resources required to carry out the proposed research. If the SRG recommends an adjustment in the project budget, the recommended adjustment will be in terms of an entire module.

The "Biographical Sketch" information will be used by the SRG in assessing each key individual's qualifications for a specific role in the proposed project as well as to evaluate the overall qualifications of the research team.

Following peer review, for applications being considered for award, the IC will request from the applicant information about "Other Research Support." Additional budget information will be requested prior to award only under special circumstances.

NIH will attempt to make awards at or close to the level of total direct costs recommended by the SRG, taking other support into account. In unusual situations, an IC may have to reduce the funding amount to accommodate the IC's cost management plan.

The award budget will be a non-categorical budget specifying approved total direct costs and F&A costs, if applicable.

Post-Award Administration

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

As indicated in this section, modular awards are subject to SNAP.

Grantees may request administrative supplements as under non-modular awards.

SUPPORT OF SCIENTIFIC MEETINGS (CONFERENCE GRANTS)

General

NIH supports scientific meetings, conferences, and workshops (hereafter "conferences") that are relevant to its scientific mission and to public health under the R13 and U13 activity codes. NIH's support of conferences is contingent on the interests and priorities of the individual ICs. 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. Further, awards must be issued prior to the start date of the conference.

Applicability

This section applies to domestic and international conferences. Some of these policies differ from the coverage in Subpart A, while others are in addition to that coverage. The following subsections indicate how they relate to Subpart A. If an area is not addressed in this section, the Subpart A coverage applies, e.g., program income.

Questions concerning the allowability of conference activity under research grants should be directed to the designated 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 a scientific or professional society, 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://www.nih.gov/grants/guide.

Public Policy Requirements and Objectives

In addition to any applicable public policy requirements and objectives specified in Subpart A, conference grant applicants must comply with the *"Guidelines on the Inclusion of Women, Minorities, and Persons with Disabilities in NIH-Sponsored and/or-Supported Intramural and Extramural Meetings and Conferences"* (available through the NIH/OER Home Page at http://www.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 for conference grants 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, organization, 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 also may be reviewed by the IC's National Advisory Council or Board.

Funding

Grants or cooperative agreements may be used to provide conference support. A cooperative agreement may be awarded if the 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 report of satisfactory progress 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 Subpart A, **no costs other than those specified in this subsection 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" in this subsection.)

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."

Honoraria: Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or admiration may not be paid from grant funds. 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" in this subsection.

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 proposed per diem or subsistence allowance must take this into consideration.

Transportation costs for attendees and participants at the conference may not exceed coach class fares. In all cases, U.S. flag carriers will be used where possible (see "Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Travel").

With the exception of local mileage, grant funds may not be used to pay per diem or expenses 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 developed in whole or in part with NIH funds, the material may be distributed free of charge. If the grantee organization charges for the material, the sales proceeds are considered program income, and must be accounted for as specified in the NGA and reported on the Financial Status Report (see "Reporting and Record Retention" in this subsection).

Unless otherwise provided in the terms and conditions of the award, the grantee is free to arrange for copyright of any publication resulting from an NIH-supported conference. However, any such copyrighted publication shall be subject to a nonexclusive, irrevocable, royalty-free license to the 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/Final Report

For single conferences, a final report of the conference must be submitted to the awarding IC within 90 days after the end of the project period (competitive segment). 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.

Under multiple-year awards, i.e., ones that support more than one conference, NIH requires an annual progress report that contains a description of specific plans for the next award period, in similar detail and format as a single conference. The annual progress report must be at least 6 months before the next scheduled conference. The final progress report should be submitted within 90 days after the end of the project period.

With the approval of the IC, copies of proceedings or publications resulting from the conference(s) may be substituted for the final report, provided that they contain the information specified for inclusion in the final report.

Expenditure Report

A Financial Status Report is required from the grantee within 90 days after the end 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 in this section. 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 of the approved project (see "Administrative Requirements—Changes in Project and Budget").

The following information must be provided to NIH as part of a competing application:

- 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, unless the application is for a modular award (see "Modular Applications and Awards" in this Subpart); and

The signature of the authorized organizational official on the application signifies that the applicant organization and all proposed consortium participants understand and agree with the following statement:

> "The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy."

NIH may request additional information 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 in this section.

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

It is the grantee organization's responsibility to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved assurance and IRB approval of the research consistent with 45 CFR Part 46, and to comply with NIH prior approval requirements related to the addition of sites not included in the approved application (see "Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements"). The list of organizations with approved assurances is available at the OHRP web site http://ohrp.osophs.dhhs.gov

Application of Cost Principles

The grantee is responsible for ensuring that the applicable government-wide cost principles and NIH cost policies described in "Cost Considerations—Allowability of Costs/Activities" are included in consortium agreements. For example, a university grantee must flow down the cost principles of OMB Circular A-122 to a consortium participant that is a non-profit research organization.

Approval Authorities

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

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

Tangible Personal Property

Exempt Property

If the grantee provides exempt property to a consortium participant or authorizes a consortium participant to purchase property that would be considered exempt if acquired by the grantee, the grantee may vest title in the consortium participant upon transfer or purchase or may reserve the right to do so at a later time. The grantee also may establish its own use, disposition, and accountability requirements, provided they are consistent with the NIH right to transfer title (see "Administrative Requirements—Management Systems and Procedures—Property Management System Standards—Equipment and Supplies").

Nonexempt Property

If the grantee provides nonexempt property to a consortium participant or authorizes a consortium participant to purchase property that would be considered nonexempt if purchased by the grantee, title to such property must remain with the grantee or be vested in the grantee upon acquisition of the property. The grantee may establish use, accountability, and disposition requirements for the property, provided they are consistent with, and do not impair, the grantee's ability to comply with the requirements of 45 CFR 74 or 92, as appropriate.

Intellectual Property

See "Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical 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 aggregate annual expenditures of $300,000 or more under applicable Federal awards, the grantee must receive a copy of that organization's A-133 audit and take appropriate action based on any findings that relate to the consortium agreement. If a consortium participant will not reach that expenditure threshold, the grantee is responsible for monitoring the organization's activities to ensure compliance with NIH requirements. The grantee may not require a consortium participant to have an audit and charge the audit costs to NIH grant funds unless required or authorized by OMB Circular A-133 or 45 CFR 74.26(d).

Written Agreement

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

- Identification of the PI and individuals responsible for the research activity at each consortium participant along with their roles and responsibilities;
- Procedures for directing and monitoring the research effort;
- Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, and procedures for review and approval of expenditures of grant funds at each organization;
- If different from those of the grantee, a determination of policies to be followed in such areas as travel reimbursement and salaries and fringe benefits (the policies of the consortium participant may be used as long as they meet NIH requirements);
- Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances (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, Intellectual Property Rights, and Sharing Biomedical 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; and
- As appropriate, provisions regarding property (other than intellectual 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 FOREIGN COMPONENTS

General

Most of the policies contained in Subpart A of this part apply to NIH grants made to foreign institutions and international organizations (hereafter "foreign grants"), including the requirements of 45 CFR Part 74 or 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 in this section. This section also includes policies that apply to domestic grants with a 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 foreign component. For purposes of this policy, a "foreign component" is defined as performance of any significant element or segment of the project outside the 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 "foreign component."

See "Support of Scientific Meetings (Conference Grants)" 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 objectives of the 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

A complete listing of public policy requirements and objectives and their applicability to foreign grants is contained in Table II-1. Several of the public policy requirements and objectives are highlighted in this subsection.

Research Misconduct. This public policy requirement 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 consortium participants under domestic or foreign grants also 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 women, members of minority groups, and children in research design as specified in "Public Policy Requirements and Objectives—Requirements for Inclusiveness in Research Design."

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

Lobbying. The requirements of "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Lobbying," including disclosure reporting, apply to foreign grants.

Debt. Foreign applicants are required to provide a certification of 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 subject to the certification requirement concerning suspension or debarment nor 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 IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government.

Funding and Payment

The application budget, requests for funds, and financial reports (see "Reporting and Record Retention" in this section) 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 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 III for address and telephone and fax numbers).

Allowability of Costs/Activities

The costs that are generally allowable under grants to domestic organizations also are 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

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 scope and requires NIH prior approval. The transfer of work by a domestic grantee to a foreign component always requires NIH prior approval even if it does not constitute a change in scope.

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

Reporting and Record Retention

Foreign grantees must submit annual FSRs in U.S. dollars, whether or not they are under SNAP. This is due to the fact that foreign grantees are not paid through PMS and, therefore, do not submit the SF-272 (which NIH uses in lieu of the annual FSR for domestic awards under SNAP). The currency rate in 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 Subpart A due to the recipient's status as a Federal institution. This section specifies those differences as well as differences in treatment among different Federal institutions. In addition, this section addresses the policies that apply to payments to (or on behalf of) Federal employees under grants, including grants awarded to organizations other than Federal institutions.

Eligibility

In general, Federal institutions are eligible to receive NIH grants, including research project grants and training grants. Federal institutions also must meet the eligibility requirements of the grant program from which support is sought. PHS organizational segments, other than 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 or 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 also must ensure that its own authorizing legislation will allow it to receive NIH grants and to be able to comply with the award terms and conditions.

A document 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 organizational 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.

Department of Veterans Affairs (VA)-University Affiliations

Investigators with joint appointments at a Department of Veterans Affairs (VA) hospital (medical center) (VAMC) and an affiliated university must have a memorandum of understanding (MOU) that specifies the title of the investigator's appointment, the responsibilities (at both the university and the VAMC) of the proposed investigator, and the percentage of effort available for research.

The MOU must be signed by the appropriate officials of the grantee organization and the VAMC and must be updated at least annually. The joint VA/university appointment of the investigator constitutes 100 percent of his or her total professional responsibilities. However, NIH will recognize such a joint appointment only when a university and an affiliated VA hospital are the parties involved.

A grant application from a university may request the university's share of an investigator's salary in proportion to the effort devoted to the research project. The individual's institutional base salary as contained in their university appointment determines the base for computing that request.

The signature of the authorized organizational official (of the submitting university) on an application to NIH that includes such an arrangement certifies that (1) the individual whose salary is included in the application serves under a joint appointment documented in a formal MOU between the university and the VA, and (2) there is no possibility of dual compensation for the same work or of an actual or apparent conflict of interest.

Under the above-described mode, there is no involvement of a VA-affiliated non-profit research corporation (VANPC). VANPCs are eligible to apply for and receive NIH grants in their own right as non-profit organizations. The limitations on the payment of Federal salaries apply (see "Allowability of Costs/Activities" in this section).

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 by 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" in this subsection.

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 considered part-time Federal employees because of service on advisory groups

or as a result of a formal consulting arrangement with a Federal agency. (See the HHS Standards of Conduct at 45 CFR 73, Subpart J for additional guidance.)

The following four specified types of costs are the only ones that can be charged to NIH grants on behalf of Federal employees, whether by a grantee or a consortium participant, and under the conditions specified only. Applicants/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 designated 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, no salary or fringe benefit payments may be made from NIH grant funds to support career, career-conditional, or other Federal employees (civilian or uniformed services) with permanent appointments provided for under existing position ceilings of a given Federal component. While the level of effort required for the research project must be allowed by the employing agency as part of the individuals' official duties, salary costs associated with an individual participating in an official capacity as a Federal employee are not allowable costs under an NIH grant. Payments to temporary employees specifically hired to assist in the performance of an NIH grant are allowable.

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, in proportion to the level of effort devoted to the project. Therefore, if the PI has a part-time appointment with the VANPC, an appropriate portion of the individual's salary that would otherwise be paid by the non-profit VANPC may be charged to the NIH grant. An NIH grant may

not be the source of funding for an increase in an investigator's salary regardless of the type of entity with which the investigator holds an appointment (e.g., university, VA, or VANPC).

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

- 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).

- A PHS Commissioned Officer on leave-without-pay (LWOP) if

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

  - 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

  - The parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.

- A civil service employee participating in a grant to a non-Federal organization and the following conditions are met:

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

  - 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.

  - 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 from Federal salary if the individual were not participating in the grant.

- The parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.

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.

Reporting Requirements

Federal institutions must submit annual FSRs regardless of whether the award is subject to SNAP. This is due to the fact that these grants are paid by the NIH Office of Financial Management rather than through the Payment Management System.

GRANTS TO FOR-PROFIT ORGANIZATIONS

General

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

Eligibility

For-profit organizations are eligible to 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, generally will 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 under a grant is considered to be an amount in excess of actual allowable direct and F&A (indirect) costs. A profit or fee may be paid to a contractor providing routine goods or services.

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 personal property title and management. Exceptions to those requirements for for-profit organizations are indicated below.

Intellectual Property: Inventions and Patents

As described in "Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical 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 "Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources—Inventions and Patents" 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 III for address and telephone number).

To the extent authorized by 35 U.S.C. 205, the Government will not make public any information 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 "Small Business Innovation Research and Small Business Technology Transfer Programs" for requirements specific to those programs.

Disposition of royalties or licensing fees earned on patents and inventions arising out of activities supported by 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

The requirements for non-Federal audits of for-profit organizations are specified in 45 CFR 74.26(d). A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $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 pro-

vides for-profit organizations two options regarding the type of audit that will satisfy the audit requirements. The grantee either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), GPO stock # 020-000-00-265-4, of all the HHS awards; or (2) an audit that meets the requirements of OMB Circular A-133.

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

The Government Auditing Standards are available electronically at http://www.gao.gov/govaud/ybk01.htm. Audits 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 end of the organization's fiscal year. The address is:

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

For-profit organizations expending less than $300,000 a year are not required to have an annual audit for that year but must make their grant-related records available to NIH or other designated officials for review or audit.

Small Business Innovation Research and Small Business Technology Transfer Programs

NIH is 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 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 either 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. As an eligibility criterion, NIH also requires the PI to 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 U.S.-owned small business concern. 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, 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 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.)

Generally, under SBIR Phase I awards, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the 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).

Generally under SBIR Phase II awards a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the 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—Standards of Conduct—Financial Conflict of Interest") do not apply to Phase I of the SBIR/STTR programs.

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/or 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 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 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 objectives 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").

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 organizations 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 to the NIH IC awarding office.

SBIR/STTR grantees are covered by 37 CFR 401 with respect to inventions and patents (see "Intellectual Property: Inventions and Patents" in this section).

RESEARCH PATIENT CARE COSTS

General

This section provides NIH policy on the determination and reimbursement of research patient care costs under grants. This general policy is intended to be applied in conjunction with the requirements of 45 CFR 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 in this section.

Definitions

Research Patient Care Costs are the costs of routine and ancillary services provided by hospitals to individuals participating in research programs. The costs of these services normally are assigned to specific research projects through the development and application of research patient care rates or amounts (hereafter "rates"). Research patient care costs **do not include**: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors, (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or in an affiliated medical school/university based on an 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 participating in a research protocol.

Routine Services are the regular room services, minor medical and surgical supplies, and the use of equipment and facilities, for which a separate charge is not customarily made.

Ancillary Services are those special services for which charges 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 usually will 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, expects to incur over $100,000 in patient care costs in any single budget period on a single NIH grant must either have in place or take steps to negotiate a research patient care rate agreement with the cognizant 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 expect to incur $100,000 or less in research patient care costs (as provided in this paragraph) and consortium participants/contractors under grants are subject to the requirements specified in the subsection on "Special Procedures for Certain Hospitals" below. Failure to negotiate a research patient care rate with DCA when required may result in the disallowance of all research patient care costs charged to a grant.

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 individuals who would not have been hospitalized or received such tests or services except for their participation in the research study. Any such exceptions should be documented in the grantee's records. These individuals may include:

- 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 hospitalization expenses in some other hospital but has no responsibility to pay in the hospital in which the approved clinical research is being conducted.

- Sick 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 also should be excluded if such costs are part of the S&W base. If a "total direct costs" base is used to compute and claim F&A costs, the above-mentioned "hospital-type" salaries also must be excluded from the base as well as any other base costs chargeable to the grant through the application of a research patient care rate.

If the grant or a consortium agreement/contract under a grant provides funding exclusively for research patient care activities, no F&A costs 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 that the grantee expects to incur. 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 also is a direct recipient of other HHS awards and in that capacity has established a rate with DCA.

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

If a participating hospital expects to 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 III for NCRR contact information).

Part III: 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 in this Part. These addresses should not be used for express mail or other types of hand-deliveries. The IC should be contacted to obtain the address to use for express mail.

For each IC that awards grants, a listing is provided for the 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 also is included. Requests related to particular applications submitted or grants awarded should be directed to the individual(s) specified in formal communications from NIH, e.g., in the Notice of Grant Award.

INSTITUTES AND CENTERS

Fogarty International Center (FIC) http://www.nih.gov/fic	
Chief Grants Management Officer Building 31C, Room B2C39, MSC-2220 Bethesda, MD 20892-2220 301/496-1653 301/402-0779 (fax)	Extramural Program Official Building 31C, Room B2C02, MSC-2220 Bethesda, MD 20892-2220 301/496-1415 301/402-2173 (fax)
National Cancer Institute (NCI) http://www.nci.nih.gov	
Chief Grants Management Officer 6120 Executive Boulevard Executive Plaza South, Room 243, MSC-7150 Bethesda, MD 20892-7150 301/496-7753 301/402-3409 (fax)	Extramural Program Official Executive Plaza North, Room 600C, MSC-7405 Bethesda, MD 20892-7405 301/496-5147 301/402-0956 (fax)
National Center for Complementary and Alternative Medicine (NCCAM) http://www.nccam.nih.gov	
Chief Grants Management Officer 6707 Democracy Boulevard Suite 106, MSC-5475 Bethesda, MD 20892-5475 301/594-9102 301/480-3621 (fax)	Extramural Program Official Building 31, Room 5B58, MSC-2182 Bethesda, MD 20892-2182 301/496-4792 301/402-4741 (fax)
National Center for Research Resources (NCRR) http://www.ncrr.nih.gov	
Chief Grants Management Officer 6705 Rockledge Drive Rockledge I, Room 6086, MSC-7965 Bethesda, MD 20892-7965 301/435-0836 301/480-3777 (fax)	Extramural Program Official Building 31, Room 3B11, MSC-2128 Bethesda, MD 20892-2128 301/496-6023 301/480-3658 (fax)
National Eye Institute (NEI) http://www.nei.nih.gov	
Chief Grants Management Officer 6120 Executive Boulevard Executive Plaza South, Room 350, MSC-7164 Bethesda, MD 20892-7164 301/435-8179 301/496-9997 (fax)	Extramural Program Official 6120 Executive Boulevard Executive Plaza South, Room 350, MSC-7164 Bethesda, MD 20892-7164 301/496-5301 301/402-0528 (fax)

National Heart, Lung and Blood Institute (NHLBI) http://www.nhlbi.nih.gov	
Chief Grants Management Officer 6701 Rockledge Drive Rockledge II, Room 7160, MSC-7926 Bethesda, MD 20892-7926 301/435-0144 301/480-3310 (fax)	Extramural Program Official 6701 Rockledge Drive Rockledge II, Room 7100, MSC-7922 Bethesda, MD 20892-7922 301/435-0260 301/480-3460 (fax)
National Human Genome Research Institute (NHGRI) http://www.nhgri.nih.gov	
Chief Grants Management Officer Building 31, Room B2B34, MSC-2031 Bethesda, MD 20892-2031 301/496-7858 301/402-1951 (fax)	Extramural Program Official Building 31, Room B2B07, MSC-2033 Bethesda, MD 20892-2033 301/435-5536 301/480-2770 (fax)
National Institute on Aging (NIA) http://www.nih.gov/nia	
Chief Grants Management Officer 7201 Wisconsin Avenue Gateway Bldg., Room 2N212, MSC-9205 Bethesda, MD 20892-9205 301/496-1472 302/402-3672 (fax)	Extramural Program Official 7201 Wisconsin Avenue Gateway Bldg., Room 2C218F, MSC-9205 Bethesda, MD 20892-9205 301/496-9322 301/402-2945 (fax)
National Institute on Alcohol Abuse and Alcoholism (NIAAA) http://www.niaaa.nih.gov	
Chief Grants Management Officer 6000 Executive Boulevard Willco Building, Suite 504, MSC-7003 Bethesda, MD 20892-7003 301/443-4704 301/443-8381 (fax)	Extramural Program Official Building 31, Room B2B07, MSC-2033 Bethesda, MD 20892-2033 301/435-5536 301/480-2770 (fax)
National Institute of Allergy and Infectious Diseases (NIAID) http://www.niaid.nih.gov	
Chief Grants Management Officer 6700-B Rockledge Drive, Room 2116, MSC-7614 Bethesda, MD 20892-7614 301/496-7075 301/480-3780 (fax)	Extramural Program Official 6700-B Rockledge Drive, Room 2141, MSC-7610 Bethesda, MD 20892-7610 301/496-7291 301/402-0369 (fax)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) http://www.nih.gov/niams	
Chief Grants Management Officer 45 Center Drive Natcher Bldg., Room 5AS.49F, MSC-6500 Bethesda, MD 20892-6500 301/594-5278 310/480-5450 (fax)	Extramural Program Official Building 31, Room 4C32, MSC-2350 Bethesda, MD 20892-2350 301/402-1691 301/480-6069 (fax)

National Institute of Child Health and Human Development (NICHD) http:www.nichd.nih.gov	
Chief Grants Management Office	Extramural Program Official
6100 Executive Boulevard, Room 8A01A MSC-7510 Bethesda, MD 20892-7510 301/496-5001 301/402-0915 (fax)	6100 Executive Boulevard, Room 6154, MSC-7510 Bethesda, MD 20892-7510 301/435-6856 301/402-2083 (fax)
National Institute on Deafness and Other Communication Disorders (NIDCD) http://www.nih.gov/nidcd	
Chief Grants Management Officer	Extramural Program Official
6120 Executive Boulevard Executive Plaza South, Suite 400B, MSC-7180 Bethesda, MD 20892-7180 301/402-0909 301/402-1758 (fax)	6120 Executive Boulevard Executive Plaza South, Suite 400C, MSC-7180 Bethesda, MD 20892-7180 301/496-8693 301/402-6250 (fax)
National Institute of Dental and Craniofacial Research (NIDCR) http://www.nidcr.nih.gov	
Chief Grants Management Officer	Extramural Program Official
45 Center Drive Natcher Bldg., Room 4AN.44A, MSC-6402 Bethesda, MD 20892-6402 301/594-4800 301/480-8301 (fax)	45 Center Drive Natcher Bldg., Room 4AN.18E, MSC-6402 Bethesda, MD 20892-6402 301/594-4848 301/480-8138 (fax)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) http://www.niddk.nih.gov	
Chief Grants Management Officer	Extramural Program Official
6707 Democracy Boulevard 2 Democracy Plaza, Room 633, MSC-5456 Bethesda, MD 20892-5456 301/594-8854 301/480-3504 (fax)	6707 Democracy Boulevard 2 Democracy Plaza, Room 631, MSC-5456 Bethesda, MD 20892-5456 301/594-8834 301/480-3504 (fax)
National Institute on Drug Abuse (NIDA) http://www.nida.nih.gov	
Chief Grants Management Officer	Extramural Program Official
6001 Executive Boulevard Neuroscience Center, Room 3119, MSC-3131 Bethesda, MD 20892-3131 301/443-6710 301/594-6849 (fax)	6001 Executive Boulevard Neuroscience Center, Room 3158, MSC-9547 Bethesda, MD 20892-9547 301/443-2755 301/443-0538 (fax)
National Institute of Environmental Health Sciences (NIEHS) http://www.niehs.nih.gov	
Chief Grants Management Officer	Extramural Program Official
P.O. Box 12233 Research Triangle Park, NC 27709 919/541-2749 919/541-2860 (fax)	P.O. Box 12233 Building 3, Room 301 Research. Triangle Park, NC 27709 919/541-7723 919/541-2843 (fax)

National Institute of General Medical Sciences (NIGMS) http://www.nigms.nih.gov	
Chief Grants Management Officer 45 Center Drive Natcher Bldg., Room 2AN.50B, MSC-6200 Bethesda, MD 20892-6200 301/594-5135 301/480-2554 (fax)	Extramural Program Official 45 Center Drive Natcher Bldg., Room 2AN.24G, MSC-6200 Bethesda, MD 20892-6200 301/594-3910 301/480-1852 (fax)
National Institute of Mental Health (NIMH) http://www.nimh.nih.gov	
Chief Grants Management Officer 6001 Executive Boulevard Neuroscience Center, Room 6115 Bethesda, MD 20892- 301/443-2811 301/443-6885 (fax)	Extramural Program Official 6001 Executive Boulevard Neuroscience Center, Room 6154 Bethesda, MD 20892- 301/443-5047 301/443-9474 (fax)
National Institute of Neurological Disorders and Stroke (NINDS) http://www.ninds.nih.gov	
Chief Grants Management Officer 6001 Executive Boulevard Neuroscience Center, Room 3290, MSC-9537 Bethesda, MD 20892-9537 301/496-9231 301/402-0219 (fax)	Extramural Program Official 6001 Executive Boulevard Neuroscience Center, Room 3309, MSC-9537 Bethesda, MD 20892-9190 301/496-9248 301/402-4370 (fax)
National Institute of Nursing Research (NINR) http://www.nih.gov/ninr	
Chief Grants Management Officer 45 Center Drive Natcher Bldg., Room 3AN.12, MSC-6300 Bethesda, MD 20892-6300 301/594-6869 301/480-8260 (fax)	Extramural Program Official Building 31, Room 5B05, MSC-2178 Bethesda, MD 20892-2178 301/594-5963 301/594-3405 (fax)
National Library of Medicine (NLM) http://www.nlm.nih.gov	
Chief Grants Management Officer 6705 Rockledge Drive Rockledge I, Suite 301, MSC-7968 Bethesda, MD 20892-7968 301/496-4221 301/402-0421 (fax)	Extramural Program Official Building 38A, Room 5N503, MSC-6075 Bethesda, MD 20892-6075 301/496-4621 301/402-0421 (fax)

OTHER NIH OFFICES

Office of Extramural Research (OER) http://www.nih.gov/grants/oer.htm	
Office of Policy for Extramural Research Administration (OPERA)	**Office of Reports and Analysis (ORA)**
Division of Grants Policy 6705 Rockledge Drive Rockledge I, Room 1190, MSC-7974 Bethesda, MD 20892-7974 301/435-0949 301/435-3059 (fax)	Division of Extramural Outreach and Information Resources 6701 Rockledge Drive Rockledge 2, MSC-7910 Bethesda, MD 20892-7910 301/435-0714
Inventions and Extramural Reporting Branch Rockledge I, Room 1136, MSC-7750 Bethesda, MD 20892-7974 301/ 435-1986 301/480-0272 (fax)	
Office of Laboratory Animal Welfare (OLAW) http://grants.nih.gov/grants/olaw/olaw.htm	
6705 Rockledge Drive Rockledge I, Suite 1050, MSC-7982 Bethesda, MD 20892-7982 301/496-7163	
Center for Scientific Review (CSR) http://www.csr.nih.gov	
6705 Rockledge Drive Rockledge II, MSC-7776 Bethesda, MD 20892-7776 Referral Office 301/435-0715	
Office of Biotechnology Activities (OBA) http://www4.od.nih.gov/oba/	
6705 Rockledge Drive, Suite 750, MSC-7985 Bethesda, MD 20892-7985 301/496-9838	
Office of Financial Management (OFM) http://www4.od.nih.gov/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 301/402-1801 (fax)	Hard-copy submission of Financial Status Reports: Building 31, Room B1B11 MSC-2052 Bethesda, MD 20892-2052 301/496-5287

Office of Acquisition Management and Policy (OAMP) Division of Financial Advisory Services http://ocm.od.nih.gov/dfas/dfas.htm	
6100 Executive Boulevard, Room 6B05, MSC-7540 Bethesda, MD 20892-7540 301/496-4401 301/402-0177	

OTHER HHS OFFICES

Office of the Inspector General (OIG)	
OIG Hotline Attn: HOTLINE 330 Independence Avenue, SW Washington, DC 20201-800-HHS-TIPS (1-800-447-8477) e-mail: HTips@os.dhhs.gov http://www.dhhs.gov/progorg/oei/hotline/hhshot.html	Questions concerning A-133 audit requirements: National External Audit Review Center Office of Audit Services 323 West 8th Street Lucas Place, Room 514 Kansas City, Missouri 64105 800/732-0679 816/374-6714 (voice) 816/374-6727 (fax)
Office for Human Research Protections (OHRP) http://ohrp.osophs.dhhs.gov	
6100 Executive Boulevard, Suite 3B01, MSC-7507 Rockville, MD 20892-7507 301/496-7005	
Office of Research Integrity (ORI) http://ori.dhhs.gov	
5515 Security Lane, Rockwall II, Suite 700 Rockville, MD 20852 301/443-5300 301/594-0042 (fax)	
Departmental Appeals Board (DAB) http://www.hhs.gov/dab	
330 Independence Avenue, SW Washington, DC 20201 202/690-5501 202/690-5863 (fax)	
Office for Civil Rights (OCR) http://www.hhs.gov/ocr	
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 (PMS)** http://www.dpm.psc.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 (DCA)	
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)	1200 Main Tower Room 1130 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 94102 415/437-7820 415/437/7823