



**U.S. Department of Health and Human Services  
Public Health Service  
Grant Application (PHS 398)**

**PART III**

**Policies, Assurances, Definitions,  
and Other Information**

## Part III. Policy, Assurances, Definitions, and Other Information

This section contains definitions, information on policy and additional guidance relating to submission of traditional, solicited and unsolicited, investigator-initiated, research project grant and cooperative agreement applications to PHS. Refer to the PHS 398 [Foreword](#), [Grants Information](#) (GrantsInfo), and [Grants Policy Statement](#) sections for additional sources of information.

### TABLE OF CONTENTS

<b>I. POLICY</b> .....	<b>1</b>
A. Applications That Include Consortium/Contractual Facilities and Administrative Costs.....	1
B. Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Mechanism .....	1
C. Revised NIH Policy on Submission of a Revised (Amended) Application.....	2
D. Policy on the Acceptance for Review of Unsolicited Applications That Request \$500,000 or More in Direct Costs.....	3
E. Resource Sharing .....	4
F. Inventions and Patents.....	5
G. Just-In-Time Policy.....	5
H. Other Support.....	6
I. Graduate Student Compensation.....	7
J. DUNS Number .....	8
<b>II. ASSURANCES AND CERTIFICATIONS</b> .....	<b>9</b>
A. Human Subjects.....	9
B. Research on Transplantation of Human Fetal Tissue .....	11
C. Research Using Human Embryonic Stem Cells.....	11
D. NIH Policy on the Inclusion of Women and Minorities in Clinical Research.....	11
E. NIH Policy on Inclusion of Children .....	13
F. Vertebrate Animals.....	13
G. Debarment and Suspension.....	14
H. Drug-Free Workplace .....	14
I. Lobbying.....	14
J. Nondelinquency on Federal Debt.....	15
K. Research Misconduct.....	15
L. Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination).....	16
M. Research Involving Recombinant DNA, including Human Gene Transfer Research.....	16
N. Financial Conflict of Interest .....	17
O. Smoke- Free Workplace.....	17
P. PHS Metric Program .....	17
Q. Prohibition on Awards to 501(c)4 Organizations That Lobby .....	17
R. Prohibited Research.....	17
S. Select Agents and Toxins .....	18
<b>III. DEFINITIONS</b> .....	<b>19</b>
<b>IV. GENERAL INFORMATION</b> .....	<b>24</b>
A. Research Grant Mechanisms.....	24
B. Mail Addressed to the National Institutes of Health.....	26

C. Government Use of Information Under Privacy Act .....27  
D. Information Available to the Principal Investigator .....27  
E. Information Available to the General Public .....27

# I. Policy

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## A. Applications That Include Consortium/Contractual Facilities and Administrative Costs

See: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html>.

NIH broadens the scope of [Notice OD-04-040](#) to apply to all applications involving consortium/contractual facilities and administrative (F&A) costs, regardless of budget amount or budget format (e.g., modular and non-modular).

This policy applies to all solicited and investigator-initiated applications. For solicited applications, this policy change now applies to all currently active announcements (Request for Applications and Program Announcements), regardless of the announcement issue date.

This policy is particularly relevant to all applications that include a limitation on direct costs. While consortium F&A costs will continue to be requested and awarded, applicants will now separate these costs when determining if a budget exceeds a direct cost limit.

This policy impacts eligibility to submit a modular budget. The modular budget format continues to be used for applications requesting \$250,000 or less in direct costs per year. However consortium/contractual F&A costs are no longer factored into this direct cost limit. They may be requested in addition to the \$250,000.

The policy also impacts applications requesting a budget of \$500,000 direct costs or more for any year. These applications continue to require prior approval from Institute/Center staff; however this limit is now exclusive of any consortium F&A costs.

Note: The implications of this policy do not affect the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs since the statutory budget guidelines are based on total costs, not

direct costs. SBIR/STTR applicants should continue to use the PHS 398 grant application forms in accordance with the instructions in the current [Omnibus Solicitation for SBIR/STTR applications](#) and the PHS 398.

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## B. Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Mechanism

See <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-019.html>.

The majority of grant applications submitted to NIH each year are investigator-initiated. However, the Institutes and Centers of NIH also solicit grant applications on specific topics through the use of Requests for Applications (RFAs). Resubmissions of grant applications fall into the following categories:

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

Since an RFA often has special considerations of eligibility, scientific scope, and review criteria, it is felt that most unfunded applications should be resubmitted as **new** applications. Similarly, a change of grant mechanism (from an R01 to an R21 or from an R03 to an R01, for example) usually involves a change of eligibility criteria, application characteristics, dollar limits, time limits, or review criteria. This also suggests that consideration as a new application is the most appropriate course. Because the application will be new, it will be easier to conform to the new application requirements, which should be an advantage to the applicant in the review process. Additionally, submission of a new

application will allow the applicant to benefit fully from the NIH policy that allows an applicant to submit two revisions (see <http://grants.nih.gov/grants/policy/amendedapps.htm>).

**NEW APPLICATIONS:** The new application must be submitted on the scheduled due dates for new applications (see <http://grants.nih.gov/grants/funding/submissionschedule.htm>). It must not include an Introduction describing the changes and improvements made and the text must not be marked to indicate the changes. Although the investigator may still benefit from the previous review, the applicant should not explicitly address reviewers' comments. The reviewers will not be provided with the previous Summary Statement. The investigator will be allowed to submit the new application and up to two revised versions of this application, should that be necessary.

**POLICY:** This general policy on application resubmission, stated below, applies to all grant mechanisms that might be solicited via an RFA and to instances where there is a change in mechanism. There may, however, be exceptions to this policy, which will be clearly identified in the original RFA or in a follow-up RFA.

1. When an application that was submitted in response to an RFA is not funded and the investigator wishes to resubmit an application on this topic as an investigator-initiated application, it is to be submitted as a **new** application, unless provisions for submission of a revised application are clearly delineated in the RFA. In addition, if a subsequent RFA specifically solicits revisions of unfunded applications from a previous RFA, the instructions in the second RFA should be followed. In all other cases, applications submitted in response to an RFA and then resubmitted as an investigator-initiated application must be submitted as a **new** application.

2. When a previously unfunded application, originally submitted as an investigator-initiated application is to be submitted in response to an RFA, it is to be prepared as a **new** application.

3. When an unfunded application that was reviewed for a particular research grant mechanism (for example, R01) is to be submitted for a different grant mechanism (for example, R03), it is to be prepared as a **new** application.

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## C. Revised NIH Policy on Submission of a Revised (Amended) Application

See: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html>.

The NIH will not consider a third revision (A3) or higher amendment to an application for extramural support. There is no longer a time limit for the submission of the first and second revisions (A1 and A2). This policy applies to all NIH extramural funding mechanisms.

In submitting a revised application, it is worth noting that a lengthy hiatus after the initial submission may be marked by significant advances in the scientific field and the comments of the reviewers may no longer be relevant. Principal investigators and their institutions need to exercise their best judgment in determining the advisability of submitting a revised application after several years have elapsed.

The policy limiting the number of revisions was established following analysis of data indicating that investigators who receive initial funding for an amended application have a lower success rate in obtaining support for a follow-on competing application. The likelihood of subsequent success decreased with an increasing number of amendments. After three reviews, it was felt that it was time for investigators to take a fresh approach to their research proposals.

Investigators who have submitted three versions of an application and have not been successful often ask NIH staff how different the next application submitted has to be to be considered a new application. It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests; however, a new application following three reviews is

expected to be substantially different in content and scope with more significant differences than are normally encountered in a revised application. Simply re-wording the title and/or Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. Changes to the Research Plan should produce a significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Design and Methods sections.

In the referral process, NIH staff look at all aspects of the application, not just the title and Description (abstract). Requesting review by a different review committee does not affect the implementation of this policy. When necessary, previous applications are analyzed for similarities to the present one. Thus, identical applications or those with only minor changes will not be accepted for review.

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#### **D. Policy on the Acceptance for Review of Unsolicited Applications That Request \$500,000 or More in Direct Costs**

Applicants must seek agreement to accept assignment from Institute/Center staff at least six weeks prior to the anticipated submission of any application requesting \$500,000 or more in direct costs for any year. Note for the purposes of determining whether or not this policy applies, this \$500,000 limit now excludes any consortium F&A costs.

The NIH supports research projects with large budgets but needs to consider such awards as early as possible in the budget and program planning process. Regardless of the merit of the application or the budget justification, unanticipated requests for unusually high amounts of direct costs are difficult for NIH to manage. It is in the best interest of all parties if applicants anticipating large direct costs contact the appropriate NIH program staff as early as

possible to ensure that an Institute/Center (IC) would be willing to accept the application.

Applicants must seek agreement from IC staff at least six weeks prior to the anticipated submission of any application requesting \$500,000 or more in direct costs for any year. Note for the purposes of determining whether or not this policy applies, this limit now excludes any consortium F&A costs. If the proposed budget excluding consortium F&A costs equals or exceeds the \$500,000 level, then prior approval is required. If staff is contacted less than six weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than \$500,000, then approval should be sought even earlier.

This prior acceptance policy does not apply to applications submitted in response to RFAs or in response to other Announcements that include specific budgetary limits. Such applications must be responsive to any budgetary limits specified; however, any specified budgetary limit now excludes consortium F&A costs.

#### **PROCEDURES**

- An applicant planning to submit a grant application with \$500,000 or more in direct costs for any year (excluding consortium F&A costs) is required to contact in writing or by telephone NIH IC program staff. This contact should be made during the development process of the application but no later than six weeks before the anticipated submission date. If the IC is willing to accept assignment of the application for consideration of funding, the staff will notify the Center for Scientific Review before the application is submitted.
- The principal investigator must include a cover letter with the application. That cover letter must identify the program staff member contacted and the Institute/Center that has agreed to accept assignment of the application.

- An application received without indication of prior staff concurrence and identification of program staff contacted will be returned to the applicant without review. Therefore, NIH strongly encourages applicants to contact appropriate IC staff at the earliest possible time.

For additional information about this policy, contact the program staff at any Institute/Center. Applicants who are uncertain about which IC may have the greatest interest in the research for which support is sought should contact the NIH CSR Receipt and Referral Office at (301) 435-0715.

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## E. Resource Sharing

**1) Data Sharing Policy:** All investigator-initiated applications with direct costs greater than \$500,000 in any single year will be expected to address data-sharing in their application. Applicants are encouraged to discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application as described at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

Applicants are reminded that agreement to accept assignment of applications over \$500,000 must be obtained at least six weeks in advance of the anticipated submission date. Instructions related to the data-sharing policy as it is applied to applications and proposals responding to a specific Request for Application (RFA) or Request for Proposals (RFP) will be described in the specific solicitation. In some cases, Program Announcements (PA) may request data-sharing plans for applications that are less than \$500,000 direct costs in any single year. Reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score. Program staff will be responsible for overseeing the data-sharing policy and for assessing the appropriateness and adequacy of the proposed data-sharing plan.

NIH recognizes that data-sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as

local, state and Federal laws and regulations, including the Privacy Rule. As NIH stated in the March 1, 2002 draft data-sharing statement (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-035.html>), the rights and privacy of people who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

For more information on data-sharing, please see our website at [http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/).

**2) Sharing Model Organisms:** All applications where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources or state appropriate reasons why such sharing is restricted or not possible. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

The adequacy of plans for sharing model organisms will be considered by the reviewers when a competing application is evaluated. Reviewers will be asked to describe their assessment of the sharing plan in an administrative note, and, normally, will not include their assessment in the overall priority score.

Note unlike the data sharing requirement above, this requirement is for **all** applications.

For additional information on this policy, see the NIH Model Organism for Biomedical Research Website at: <http://www.nih.gov/science/models/>

and NIH Guide Notices OD-04-042: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>, and OD-04-066: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html>.

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## F. Inventions and Patents

According to NIH Grants Policy and Federal law, NIH recipient organizations must promptly report all inventions that are either conceived or first actually reduced to practice using NIH grant funds. Invention reporting compliance is described at <http://www.iedison.gov>. The grantee is encouraged to submit reports electronically using Interagency Edison (<http://www.iedison.gov>). Inquiries or correspondence should be directed to **Extramural Inventions and Technology Resources Branch of the Office of Policy for Extramural Research Administration, OER, NIH, 6705 Rockledge Dr., MSC 7980, Bethesda, MD 20892-7980, (301) 435-1986**. Information from these reports is retained by the NIH as confidential and submission does not constitute any public disclosure. Failure to report as described at 37CFR Section 401.14 is a violation of 35 USC 202 and may result in loss of the rights of the recipient organization.

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## G. Just-In-Time Policy

Several elements of an application are no longer required at the time the application is submitted. Instead, this information will be requested later in the review cycle (i.e., “just-in-time”) to ensure that it is current. The information eligible for just-in-time submission includes:

- **Current Other Support:** See [Other Support](#) section for policy information. Use the sample format provided on the Other Support Format Page ([MS WORD](#) or [PDF](#)). For all Key Personnel, provide details on how you would adjust any budgetary, scientific, or effort overlap if this application is funded.

For **Career Development Award** applicants, information on all active support for the candidate, sponsor(s), co-sponsor(s), and Key Personnel may be requested by the awarding component prior to award.

- **Certifications:**
  - If human subjects are involved, provide the assurance type and number (if not previously provided) and the Certification of IRB Review and Approval. Pending or out-of-date approvals are not acceptable.
  - If vertebrate animals are involved and this information was not previously provided on the Face Page of the application, provide assurance number, verification of IACUC approval with date, and any IACUC-imposed changes. Pending or out-of-date approvals are not acceptable.
- **Human Subjects Education:** For grants involving Human Subjects, provide certification that each person identified under Key Personnel involved in the design or conduct of research involving human subjects has completed an educational program in the protection of human subjects. For further information refer to the separate section on [Required Education in the Protection of Human Research Participants](#).

In addition, applicants for **Research Career Development Awards** will be asked to provide detailed, categorical budget and narrative justification pages (Form Page 4 and Form Page 5) prior to award.

Applicants are advised to submit this information (countersigned by an authorized business official) only when requested by the awarding component. Guidance for submitting this information will be provided at the time of the request. Alternatively, this information may now be submitted using the Just-In-Time feature of the eRA Commons found in the **Status** section. For information on the Commons see: <https://commons.era.nih.gov/commons/index.jsp>.



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## H. Other Support

Do not submit information on Other Support with the application beyond that required in the biographical sketch. If this information is included at the time of application, processing may be delayed or the application may be returned to the applicant without review.

Information on Other Support is required for all applications that are to receive grant awards; NIH will request complete and up to date information from applicants at an appropriate time **after peer review**. The Institute/Center scientific program and grants management staff will review this information prior to award.

Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. It is used by reviewers for the "investigator" review criterion. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date "other support" information from you *after* peer review. This information will be used to check that the proposed research has not already been Federally-funded.

### OTHER SUPPORT POLICY

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included.

Information on Other Support assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that

only funds necessary to the conduct of the approved project are included in the award.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.

Commitment overlap occurs when a person's time commitment exceeds 100 percent, whether or not salary support is requested in the application. While information on other support is only requested for Key Personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent.

Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source. Potential scientific overlap is to be addressed by the SRG *only* by its identification in an Administrative Note in the Summary Statement.

**Resolution of Overlap.** Resolution of overlap occurs at the time of award in conjunction with applicant institution officials, the principal investigator, and awarding agency staff.

### OTHER SUPPORT INFORMATION

[OTHER SUPPORT FORMAT PAGE \(MS WORD OR PDF\)](#)

Information on Other Support should be submitted **ONLY** when requested by the NIH Institute/Center (IC).

There is no form page for Other Support. Follow the sample format on the Other Support Format Page. The sample is intended to provide guidance regarding the type and extent of information requested.

The following instructions should be followed in completing the information:

- Information on active and pending Other Support is required for Key Personnel, excluding consultants. For individuals with

no active or pending support, indicate "None." Neither the application under consideration nor the current PHS award for this project should be listed as Other Support. Do not include Other Support for individuals listed as "Other Significant Contributors" unless their involvement has changed so that they now meet the definition of "key personnel."

- If the support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, principal investigator, and source for the overall project, and provide all other information for the subproject only.

### **INSTRUCTIONS FOR SELECTED ITEMS**

*Project Number:* If applicable, include a code or identifier for the project.

*Source:* Identify the agency, institute, foundation, or other organization that is providing the support.

*Major Goals:* Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

*Dates of Approved/Proposed Project:* Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

*Annual Direct Costs:* In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

*Percent Effort:* For an active project, provide the level of actual effort (even if unsalaried) for the current budget period. For a pending project, indicate the level of effort as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

*Overlap:* After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application

in terms of the science, budget, or an individual's committed effort.

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## **I. Graduate Student Compensation**

The maximum amount awarded by the NIH for the support of a graduate student on a research grant or a cooperative agreement is tied to the National Research Service Award (NRSA) zero-level stipend in effect at the time the grant award is issued. The schedule for NRSA stipends can be found at

<http://grants.nih.gov/training/nrsa.htm>.

Consistent with cost principles for educational institutions described in Office of Management and Budget (OMB) Circular A-21 at section

J.41.b (<http://www.whitehouse.gov/omb/circulars/a021/a021.html>), the compensation of

graduate students supported by research grants must be reasonable. These operating

principles associated with the compensation of students performing necessary work on NIH

funded research projects are described in detail in the *NIH Grants Policy Statement* at

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part6.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm). As before, the amount

provided for compensation includes salary or wages, fringe benefits, and tuition remission.

These guidelines apply to graduate students at the grantee institution who are supported by NIH research grants and cooperative agreements and not to individuals supported by NRSA training grants and fellowships. NIH has separate appropriations to support research training under the NRSA authorization at Section 487 of the Public Health Service Act.

The stipends provided to recipients of NRSA support offset the cost-of-living during the period of training and are not considered equivalent to salaries or other forms of compensation provided to individuals supported on research grants. Nevertheless, the entry-level postdoctoral NRSA stipend provides a useful benchmark for an award amount that approximates a reasonable rate of compensation for graduate students.

Anticipated escalations in NRSA stipends (see [http://grants.nih.gov/training/nas\\_report/NIHResponse.htm](http://grants.nih.gov/training/nas_report/NIHResponse.htm)) in future years should permit annual

increases in the maximum award amount for such individuals.

For all new and competing grant and cooperative agreement awards, the NIH will provide reasonable amounts for graduate compensation, consistent with the requested budget for the position(s) and up to the currently effective NRSA zero postdoctoral stipend level. NIH staff will review the compensation requested for graduate students on competing and cooperative agreement applications for which a detailed budget is submitted. NIH will neither request nor accept budgets for those applications using a modular budget format solely for the purpose of reviewing graduate student compensation. However, applicants should use this policy when estimating the number of modules.

When submitting detailed budgets that request support for a graduate student, grantees are reminded to request actual institutional-based compensation and to provide information justifying the requested compensation level. If this information is not provided, NIH staff will obtain this information from the institution's business office for any request that appears excessive.

NIH institutes and centers will review the requested compensation level and, if considered reasonable, will award the actual amount requested, up to a maximum equal to the NRSA zero level postdoctoral stipend. Revised budgets submitted solely to adjust requested levels for graduate students will not be accepted.

Institutions may continue to rebudget funds to charge more than the awarded amount provided that OMB cost principles requiring reasonable compensation are observed. In general, graduate student compensation will not be considered reasonable if in excess of the amount paid to a first-year postdoctoral scientist at the same institution performing comparable work.

System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. Form Page 1 includes a field for the organization's DUNS number. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An authorized organizational official should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an authorized organizational official should complete the [US D&B D-U-N-S Number Request Form](#) or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual principal investigators do not need to register for a DUNS.

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## J. DUNS Number

Applicant organizations **must have** a DUN and Bradstreet (D&B) Data Universal Numbering

## II. Assurances and Certifications

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application.

The assurances listed and explained below may or may not be applicable to your project, program, or type of applicant organization. There are a number of additional public policy requirements with which applicants and grantees must comply. Contact your institution's research grant administrative office or consult the *NIH Grants Policy Statement* for additional information. A copy of the [NIH Grants Policy Statement](#) may be obtained from the NIH website (<http://grants.nih.gov/grants/policy/policy.htm>). In signing the application Face Page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with the following policies, assurances and/or certifications:

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### A. Human Subjects

(Also see [Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.](#))

The DHHS regulations for the protection of human subjects provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations stipulate that an applicant organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations require that applicant organizations proposing to involve human subjects in non-exempt research file a written Assurance of Compliance with the Office for Human Research Protections (OHRP), establishing appropriate policies and procedures for the protection of human subjects. These regulations, [45 CFR Part 46](#),

Protection of Human Subjects, are available from the OHRP, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20854, 1-866-447-4777 or (301) 496-7005.

No non-exempt research involving human subjects can be conducted under a DHHS-sponsored award unless that organization is operating in accordance with an approved Assurance of Compliance and provides verification that an appropriate Institutional Review Board (IRB) has reviewed and approved the proposed activity in accordance with the DHHS regulations. An award will not be made to an applicant unless that applicant is affiliated with an assured organization that accepts responsibility for compliance with the DHHS regulations. Foreign applicant organizations must also comply with the provisions of the regulations.

The Center of Biologics Evaluation and Research (CBER) at FDA regulates the use of biological products in humans, at the investigational and marketing phases, including somatic cell therapies and gene therapies. If your work involves these areas or preclinical research that will support later work in these areas, please see the Office of Recombinant DNA Activities Web site at <http://www4.od.nih.gov/oba/>.

Note: Under DHHS regulations to protect human subjects from research risks, certain research areas are exempt. (See [Exemption Categories](#)). Nonetheless, studies that are exempt from the human subjects regulations must still address the inclusion of women and minorities and children in clinical research in the study design. Therefore, applications will be evaluated for compliance with this policy. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable are also to be included within the term "research involving human subjects."

Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research may result in delays in the review of an application or the return of the application without review. The OHRP will make

a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. In doubtful cases, consult with the OHRP DHHS by accessing their website <http://www.hhs.gov/ohrp/> for guidance and further information.

Federal requirements to protect human subjects apply to most research on human specimens (such as cells, blood, and urine), residual diagnostic specimens and medical information. The NIH has developed a user-friendly brochure to help investigators understand how the human subjects regulations [45CFR46](#) apply to their research. You may download this brochure, entitled "Research on Human Specimens: Are You Conducting Research Using Human Subjects?" (<http://www.cancerdiagnosis.nci.nih.gov/specimens/brochure.html>).

#### **VULNERABLE POPULATIONS**

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners, or children must follow the provisions of the regulations in Subparts [B](#), [C](#), and [D](#) of [45 CFR Part 46](#), respectively, which describe the additional protections required for these populations. Relevant information may be obtained at the OHRP website (<http://www.hhs.gov/ohrp/policy/index.html>).

**REMINDER:** HHS regulations at [45 CFR Part 46, subpart C](#) describe requirements for additional protections for research involving prisoners as subjects or individuals who become prisoners after the research has started. Refer to: <http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm> for complete instructions.

[Exemptions 1-6](#) (See [Human Subjects Research Supplement](#)) do not apply to research involving prisoners or subjects who become prisoners (see [Subpart C](#)). Although Exemptions 1 and 3-6 apply to research involving children (see [Subpart D](#)), [Exemption 2](#) can only be used for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

#### **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. A data and safety monitoring plan is required for each clinical trial. This policy is in addition to any monitoring requirements imposed by [45 CFR Part 46](#).

The detailed data and safety monitoring plans must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. The establishment of data safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. 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.

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>).

#### **REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS**

NIH requires education on the protection of human research participants for all individuals identified as Key Personnel before funds are awarded for applications or contract proposals involving human subjects. For information relating to this requirement, see the following notices: (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>) and (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html>), and Frequently

Asked Questions

([http://grants.nih.gov/grants/policy/hs\\_educ\\_faq.htm](http://grants.nih.gov/grants/policy/hs_educ_faq.htm).) Prior to award, applicants will be required to provide a description of education completed in the protection of human subjects for all Key Personnel. While NIH does not endorse programs, there are curricula available that can provide guidance or that can be modified to provide training in this area. See <http://ohsr.od.nih.gov/> for computer-based training developed for NIH that can be downloaded at no charge. For information on facilitating education and developing curricula, see <http://www.nih.gov/sigs/bioethics>.

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## B. Research on Transplantation of Human Fetal Tissue

In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research on the transplantation of human fetal tissue is conducted, the applicant organization will make available, for audit by the Secretary, DHHS, the physician statements and informed consents required by section 498A (b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure DHHS access to those records, if maintained by an entity other than the applicant organization.

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## C. Research Using Human Embryonic Stem Cells

<http://stemcells.nih.gov/index.asp>

In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research using human embryonic stem cells is proposed, the applicant organization will be in compliance with the “Notice of Extended Receipt Date and Supplemental Information Guidance for Applications Requesting Funding that Proposes Research with Human Embryonic Stem Cells” (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-006.html>).

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## D. NIH Policy on the Inclusion of Women and Minorities in Clinical Research

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving [clinical research](#) unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants. See [http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm).

### NIH POLICY ON REPORTING RACE AND ETHNICITY DATA: SUBJECTS IN CLINICAL RESEARCH

Also see “[Guidance on Reporting Ethnicity/Race and Sex/Gender in Clinical Research](#)” in [Human Subjects Research Supplemental Instructions](#).

The NIH has adopted the 1997 Office of Management and Budget (OMB) revised

minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant, contract, and intramural proposals and for all active research grants, cooperative agreements, contracts, and intramural projects. The minimum standards are described in the 1997 OMB Directive 15, <http://www.whitehouse.gov/omb/fedreg/ombdir15.html>.

The 1997 OMB revised minimum standards include two ethnic categories (Hispanic or Latino, and Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. Using self-reporting or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

Collection of this information and use of these categories is required for research that meets the NIH definition of [clinical research](#).

### **Revised Minimum Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity**

The following are the ethnic and racial definitions for the minimum standard categories (1997 OMB Directive 15):

#### **Ethnic Categories:**

**Hispanic or Latino:** A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."

#### **Not Hispanic or Latino**

#### **Racial Categories:**

**American Indian or Alaska Native:** A person having origins in any of the original peoples of North, Central, or South America, and who

maintains tribal affiliations or community attachment.

**Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

**Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

**Native Hawaiian or Other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

**White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Using respondent self-report or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

When reporting these data in the aggregate, investigators should report: (a) the number of respondents in each ethnic category; (b) the number of respondents who selected only one category for each of the five racial categories; (c) the total number of respondents who selected multiple racial categories reported as the "number selecting more than one race"; and (d) the number of respondents in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed items should be designed in a way that they can be aggregated into the required categories for reporting purposes. NIH is required to use these definitions to allow comparisons to other Federal databases, especially the census and

national health databases. Federal agencies will not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

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## E. NIH Policy on Inclusion of Children

(See [Definition](#) of “child”.)

Research involving children must comply with the NIH Policy and Guidelines on the Inclusion of Children in Clinical Research. The following excerpts provide the key policy statements. Investigators should obtain full copies of the Policy and Guidelines from NIH staff, or from the NIH grants Web site under <http://grants.nih.gov/grants/funding/children/children.htm>.

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH unless there are clear and compelling reasons not to include them. Therefore, proposals for clinical research must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In addition, the involvement of children as subjects in research must be in compliance with all applicable subparts of [45 CFR Part 46](#) as well as with other pertinent Federal laws and regulations.

Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the state or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

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## F. Vertebrate Animals

NIH no longer requires Institutional Animal Care and Use Committee (IACUC) approval of the

proposed research **before NIH peer review** of an application (<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html>).

In August, 2002 NIH announced an IACUC “just-in-time” process for applications submitted for the October 1, 2002 deadline or other deadlines where the applications had a May/June 2003 Council review. The PHS policy requirement that no award may be made without an approved Assurance and without verification of IACUC approval remains in effect. The new policy gave institutions flexibility in the timing of IACUC review relative to the submission of an application and the verification of IACUC review. The policy does not require that IACUC approval be deferred. Institutional officials retain the discretion to require IACUC approval prior to NIH peer review in circumstances of their choosing if deemed necessary. As part of the NIH peer review process, the scientific review group will continue to address the adequacy of animal usage and protections in the review of an application and will continue to raise any concerns about animal welfare issues. Verification of IACUC approval will be required in a “just-in-time” fashion prior to award.

The PHS *Policy on Humane Care and Use of Laboratory Animals* requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable state or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply,



as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163.

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

No PHS award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the IACUC has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the IACUC for further review in the case of apparent or potential violations of the PHS policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

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## **G. Debarment and Suspension**

Executive Order 12549, “Debarment and Suspension,” mandated development of a Government-wide debarment and suspension system for nonprocurement transactions with Federal agencies. Executive Order 12689 and Section 2455 of the Federal Acquisition Streamlining Act of 1994 further required Federal agencies to establish regulations for reciprocal Government-wide effect across procurement and nonprocurement debarment and suspension actions. This reciprocity rule is effective for any debarment, suspension or other Government-wide exclusion initiated on or after August 25, 1995.

DHHS regulations implementing Executive Orders 12549 and 12689 and Section 2455 of the Federal Acquisition Regulation are provided in 45 CFR 76, “Government-wide Debarment and Suspension (Nonprocurement).” Changes in this Government-wide requirement (adopted in the November 26, 2003 Federal Register Notice) now implement this as a term and condition of an award.

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## **H. Drug-Free Workplace**

DHHS regulations implementing the Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D) are now provided in 45 CFR 82, “Government-wide Requirements for Drug-Free Workplace (Financial Assistance).” Changes in this Government-wide requirement (adopted in the November 26, 2003 Federal Register Notice) now implement this as a term and condition of an award.

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## **I. Lobbying**

Title 31, United States Code, Section 1352, entitled “Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions,” generally prohibits recipients of Federal grants and cooperative agreements from using Federal (appropriated) funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific grant or cooperative agreement. Section 1352 also requires that each person who requests or receives a Federal grant or cooperative agreement must disclose lobbying undertaken with non-Federal (nonappropriated) funds. These requirements apply to grants and cooperative agreements exceeding \$100,000 in total costs. DHHS regulations implementing Section 1352 are provided in 45 CFR Part 93, “New Restrictions on Lobbying.”

The complete Certification Regarding Lobbying is provided below.

“The undersigned (authorized official signing for the applicant organization) certifies, to the best of his or her knowledge and belief that:

“(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person 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 the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

“(2) If any funds other than Federally appropriated funds have been paid or will be paid to any person 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 this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form LLL, “Disclosure of Lobbying Activities,” in accordance with its instructions.

“(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

“This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.”

Standard Form LLL, “Disclosure of Lobbying Activities,” its instructions, and continuation sheet are available from GrantsInfo, National Institutes of Health, e-mail:

[GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov), (301) 435-0714.

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## J. 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 as in the case of an individual Ruth L. Kirschstein 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.

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## K. Research Misconduct

Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by (1) 42 CFR Part 50, Subpart A, “Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science” and (2) 42 CFR 94, “Public Health Service Standards for the Protection of Research Misconduct Whistleblowers” (effective on the date set forth in the final rule).

The signature of the official signing for the applicant organization on the Face Page of the application serves as certification that:

1. The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;
2. The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;

3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

"Misconduct in Science" and "Research Misconduct" are defined by the Public Health Service as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretation or judgments of data."

For further information, please contact:

Office of Research Integrity  
 Division of Education and Integrity  
 Rockwall II, Suite 700  
 5515 Security Lane  
 Rockville, MD 20852,  
 Phone: (301) 443-5300  
 Fax: (301) 594-0042 or (301) 445-5351.

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## **L. Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination)**

Before a grant award can be made, a domestic applicant organization must certify that it has filed with the DHHS Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (P.L. 88352, as amended), which prohibits discrimination on the basis of race, color, or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (P.L. 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (P.L. 94-135), which prohibits discrimination on the basis of age.

The Assurance of Compliance Form HHS 690 is available from <http://www.hhs.gov/ocr/ps690.pdf>.

Assurance of Compliance Form HHS 690 is now used in lieu of individual assurances: Form HHS 441, Civil Rights; Form HHS 641, Handicapped Individuals; Form HHS 639-A, Sex Discrimination; and Form HHS 680, Age Discrimination.

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## **M. Research Involving Recombinant DNA, including Human Gene Transfer Research**

The *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* apply to all projects (NIH-funded and non-NIH-funded) involving recombinant DNA molecules that are conducted at or sponsored by an institution that receives NIH support for recombinant DNA research. As defined by the *NIH Guidelines*, recombinant DNA molecules are either: (1) molecules that are constructed outside 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* set forth principles and standards for safe and ethical conduct of recombinant DNA research and apply to both basic and clinical research studies. The *NIH Guidelines* should be carefully reviewed and implemented to ensure that proper biosafety and containment practices are employed for all projects involving recombinant DNA research, including review by an Institutional Biosafety Committee that meets the requirements of the *NIH Guidelines*. Further, the *NIH Guidelines* include special review and reporting requirements for the conduct of human gene transfer studies (under Appendix M). Failure to comply with the *NIH Guidelines* 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. A copy of the *NIH Guidelines* is posted at the following URL: <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> and may be obtained from the NIH Office of Biotechnology Activities, 6705

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## **N. Financial Conflict of Interest**

NIH requires grantees and investigators (except Phase I SBIR/STTR applicants) to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." These requirements promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator.

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:

1. There is in effect at the organization a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
2. Prior to the expenditure of any NIH funds awarded under a new award, the organization will inform NIH of the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations;
3. The Institution will continue to make similar reports on subsequently identified conflicts; and it will make information available to NIH, upon request, as to how identified conflicting interests have been handled.

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## **O. Smoke- Free Workplace**

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in

certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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## **P. PHS Metric Program**

Consistent with Government-wide implementing regulations, 15 CFR Part 19, Subpart B and/or any other Government-wide requirements, PHS policy is to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and all other financial assistance awards. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric.

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## **Q. Prohibition on Awards to 501(c)4 Organizations That Lobby**

Organizations described in section 501(c)4 of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive grant/cooperative agreement awards. This is not to be confused with 45 CFR Part 93, Section 1352, "New Restrictions on Lobbying" [Section II.I, "Lobbying."](#)

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## **R. Prohibited Research**

### **BAN ON FUNDING OF HUMAN EMBRYO RESEARCH (SECTION 510)**

This section continues the current ban that prohibits NIH from using appropriated funds to support human embryo research. Grant, cooperative agreement, and contract funds may not be used for: "(a)...(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.208(a)(2) and section 498(b) of the Public

Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term `human embryo or embryos' includes any organism not protected as a human subject under [45 CFR Part 46](#) as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."

The NIH has published final guidelines on the allowability of Federal funds to be used for research on existing human embryonic stem cell lines. The URL is <http://stemcells.nih.gov/index.asp>.

#### **LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES (SECTION 511)**

"(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C.812). (b)The limitation in subsection (a) shall not apply when 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."

#### **RESTRICTION ON DISTRIBUTION OF STERILE NEEDLES (SECTION 505)**

"Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug."

#### **RESTRICTION ON ABORTIONS (SECTION 508)**

"(a) None of the funds appropriated under this Act, and none of the funds in any trust fund to which funds are appropriated under this Act, shall be expended for any abortion."

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### **S. Select Agents and Toxins**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The Act was implemented, in part, through regulations published by CDC at 42 CFR 73 <<http://www.cdc.gov/od/sap/docs/42cfr73.pdf>>, Select Agents and Toxins.

As a term of award, grantees who conduct research involving Select Agents (see 42 CFR 73 for the list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens) are reminded that they must complete registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Research involving select agents and recombinant DNA molecules also is subject to the NIH Guidelines for Research Involving DNA Molecules (NIH Guidelines) (see Recombinant DNA and Human Gene Transfer Research in this subsection for applicability of these guidelines).

### III. Definitions

(See also [Human Subjects Research Definitions](#).)

**AIDS Related.** Includes: (1) projects relating to the etiology, epidemiology, natural history, diagnosis, treatment, or prevention of AIDS; (2) various sequelae specifically associated with the syndrome; and (3) preparation and screening of anti-AIDS agents as well as vaccine development, including both preclinical and clinical studies. Not all applications examining various influences on T-lymphocytes or retroviruses will be appropriate for the expedited AIDS review process. Applications only indirectly related to AIDS will be evaluated by established Scientific Review Groups (SRGs) appropriate to the scientific discipline during regular NIH review cycles and should not be submitted in response to the expedited AIDS receipt dates. Applicants are urged to take note of the yearly NIH Plan for HIV-Related Research and indicate how their application addresses the NIH priorities set forth in that Plan. The Plan can be found on the NIH Office of AIDS Research homepage.

**Animal.** Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes at the applicant organization or any collaborating site or other performance site.

#### APPLICANT ORGANIZATION TYPES.

**Federal:** A cabinet-level department or independent agency of the Executive Branch of the Federal Government or any component part of such a department or agency that may be assigned the responsibility for carrying out a grant-supported program.

**State:** Any agency or instrumentality of a state government of any of the United States or its territories.

**Local:** Any agency or instrumentality of a political subdivision of government below the State level.

**Nonprofit:** An institution, corporation, or other legal entity no part of whose net earnings may

lawfully inure to the benefit of any private shareholder or individual.

**For profit:** An institution, corporation, or other legal entity, which is organized for the profit or benefit of its shareholders or other owners. A “for profit” organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons. Also see definition for Small Business Concern.

**Small Business Concern:** A small business concern is one that, at the time of award of Phase I and Phase II, meets **all** of the following criteria:

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, and is organized for profit.
2. Is at least 51% owned, or in the case of a publicly owned business, at least 51% of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.
3. Has, including its affiliates, **a number of employees not exceeding 500**, and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term “affiliates” is defined in greater detail in 13 CFR 121.3-2(a). The term “number of employees” is defined in 13 CFR 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small

Business Administration Size District Office at <http://www.sba.gov/size/>.

**Socially and Economically Disadvantaged Small Business Concern:**

A socially and economically disadvantaged small business concern is one that is at least 51% owned by (a) an Indian tribe or a native Hawaiian organization, or (b) one or more socially and economically disadvantaged individuals; **and** whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

**Women-Owned Small Business Concern:** A small business concern that is at least 51% owned by a woman or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

**Co-investigator.** An individual involved with the principal investigator in the scientific development or execution of the project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. This individual would typically devote a specific percent of effort to the project and would be identified as Key Personnel. The designation of a co-investigator, if applicable, does not affect the principal investigator's roles and responsibilities as specified in the [Grants Policy Statement](#).

**Commercialization.** The process of developing markets and producing and delivering products for sale (whether by the originating party or by others). As used here, commercialization includes both government and private sector markets.

**Consortium Agreement.** A formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific

percent of effort from the consortium organization's principal investigator and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including Facilities and Administrative costs.

**Consultant.** An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, grantees and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants may also include firms that provide paid professional advice or services.

**Consulting fees.** The fee paid by an institution to a salaried member of its faculty is allowable only in unusual cases and only if both of the following conditions exist: (1) the consultation crosses departmental lines or involves a separate operation; and (2) the work performed by the consultant is in addition to his or her regular workload.

In all other cases, consulting fees paid to employees of recipient or cost-type contractor organizations in addition to salary may be charged to PHS grant-supported projects only in unusual situations and when all of the following conditions exist: (1) the policies of the recipient or contractor permit such consulting fee payments to its own employees regardless of whether Federal grant funds are received; (2) the consulting services are clearly outside the scope of the individual's salaried employment; and (3) it would be inappropriate or not feasible to compensate the individual for these services through payment of additional salary.

For additional clarification on the allowance and appropriateness of consulting fees, refer to the [NIH Grants Policy Statement](#).

**Cooperative Agreement.** A financial assistance mechanism that will have substantial Federal scientific and/or programmatic involvement. Substantial programmatic

involvement means that after award, scientific or program staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed cooperative agreements will be published as policy announcements, Program Announcements, or Requests for Applications.

**Equipment.** An article of tangible nonexpendable personal property that has a useful life of more than one year and an acquisition cost per unit that equals or exceeds the lesser of the capitalization threshold established by the organization or \$5,000.

**Essentially Equivalent Work.** This term is meant to identify “scientific overlap,” which occurs when (1) substantially the same research is proposed for funding in more than one contract proposal or grant application submitted to the same Federal agency; **or** (2) substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; **or** (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

**Feasibility.** The extent to which a study or project may be done practically and successfully.

**Foreign Component.** The performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to: (1) the involvement of human subjects or animals; (2) extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities; or (3) any activity of the grantee that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Foreign travel for consultation is not considered a foreign component.

**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.

**Innovation.** Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of “innovation” would be new medical or biological products for improved value, efficiency, or costs.

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

Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at time of award. Applicants are encouraged to contact their offices of sponsored programs or see the [NIH Guide for Grants and Contracts](#) for current guidance on salary requirements.

**Key Personnel.** In addition to the principal investigator, Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be



included if their involvement meets the definition of Key Personnel. Consultants should also be included if they meet the definition of Key Personnel. Key Personnel must devote measurable effort to the project whether or not salaries are requested--"zero percent" effort or "as needed" are not acceptable levels for those designated as Key Personnel.

**Other Significant Contributors.** This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the projects. These individuals are typically presented at "zero percent" effort or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.

**Principal Investigator, Program Director, or Project Director.** The one individual designated by the applicant organization to direct the project or program to be supported by the grant. The principal investigator is responsible and accountable to applicant organization officials for the proper conduct of the project or program.

**Program Income.** Gross income earned by the applicant organization that is directly generated by a supported activity or earned as a result of the award. The *PHS Grants Policy Statement* or [NIH Grants Policy Statement](#) contains a detailed explanation of program income, the ways in which it may be generated and accounted for, and the various options for its use and disposition.

Examples of program income include:

- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing;
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds;

- Third party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such reimbursement occurs because of the grant-supported activity;
- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals;
- Patent or copyright royalties (exempt from reporting requirements); and
- Registration fees generated from grant-supported conferences.

**Prototype.** A model of something to be further developed and includes designs, protocols, questionnaires, software, and devices.

**Research or Research and Development (R/R&D).** Any activity that is:

- A systematic, intensive study directed toward greater knowledge or understanding of the subject studied;
- A systematic study directed specifically toward applying new knowledge to meet a recognized need;
- A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

**Research Institution.** A United States research organization that is:

- A nonprofit college or university **or**
- A nonprofit research institution, including nonprofit medical and surgical hospitals. (A "nonprofit institution" is defined as an organization that is owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.) **or**

- A contractor-operated, Federally funded research and development center, as identified by the National Science Foundation in accordance with the Government-wide Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor legislation thereto).

(Laboratories staffed by Federal employees do not meet the definition of “research institution” for purposes of the STTR program.)

**Socially and Economically Disadvantaged Individual.** A member of any of the following groups: Black Americans; Hispanic Americans; Native Americans; Asian-Pacific Americans;

Subcontinent Asian Americans; other groups designated from time to time by the Small Business Administration (SBA) to be socially disadvantaged; or any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act, 15 U.S.C. 637(a).

**Subcontract.** Any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government prime contractor calling for supplies or services required solely for the performance of the prime contract or another subcontract.

**United States.** The 50 states, territories and possessions of the U.S., Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands, and District of Columbia.

## IV. General Information

For more detailed information, visit the OER Grants website <http://grants1.nih.gov/grants/oer.htm>.

### A. Research Grant Mechanisms

The following table summarizes the major mechanisms NIH uses to fund research grants.

Type (Mechanism)	Description
<b>Research Grants</b>	
<b>Basic Research Grant (R01)</b>	<b>Basic Research Grants</b> are awarded to eligible institutions on behalf of a principal investigator to support a discrete project related to the investigator's area of interest and competence. These grants make up the largest category of NIH funding.
<b>Small Research Grant (R03)</b> <a href="http://grants.nih.gov/grants/funding/r03.htm">http://grants.nih.gov/grants/funding/r03.htm</a>	<b>Small Research Grants</b> support small research projects that can be carried out in a short period of time with limited resources for projects such as pilot or feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology and/or development of new research technology. <i>Not all awarding components accept investigator-initiated R03 applications.</i> Applicants interested in the small research grant program of PHS-awarding components other than NIH should contact an official of the appropriate PHS-awarding component (See <a href="#">Awarding Component Contact Table</a> ).
<b>Academic Research Enhancement Award (AREA) (R15)</b> <a href="http://grants.nih.gov/grants/funding/area.htm">http://grants.nih.gov/grants/funding/area.htm</a>	<b>Academic Research Enhancement Awards</b> provide support to scientists at eligible domestic institutions for small-scale health-related research projects, such as pilot research projects and feasibility studies; development, testing, and refinement of research techniques; and similar discrete research projects that demonstrate research capability. This award is directed toward those smaller public and private colleges and universities that provide undergraduate training for a significant number of the U.S. research scientists. (Applicants should use the PHS 398 with the AREA guidelines.)
<b>Exploratory/Developmental Research Grant (R21/R33)</b> <a href="http://grants.nih.gov/grants/funding/r21.htm">http://grants.nih.gov/grants/funding/r21.htm</a>	<b>Exploratory/Developmental Research Grants</b> seek to broaden the base of inquiry in fundamental biomedical research by encouraging applications for research projects that involve an especially high degree of innovation and novelty. NIH provides pilot-scale support for potentially ground-breaking ideas, methods, and systems that meet the following criteria: they lack sufficient preliminary data for feasibility to be established, their successful demonstration would have a major impact on biomedical research, and they fall within the areas supported by the awarding I/C. <i>Not all awarding components accept R21/R33 applications.</i>

Type (Mechanism)	Description
<p><b>Small Business Innovation Research Grant (SBIR: R43/R44)</b></p> <p><b>Small Business Technology Transfer Grant (STTR: R41/R42)</b></p> <p><a href="http://grants.nih.gov/grants/funding/sbir.htm">http://grants.nih.gov/grants/funding/sbir.htm</a></p>	<p><b>SBIR and STTR grants</b> are made to eligible domestic for-profit small business concerns conducting innovative research that has the potential for commercialization.</p> <p>SBIR/STTR awards are intended to stimulate technological innovation, use small business to meet Federal research and development needs, increase private sector commercialization of innovations derived from Federal research and development, and foster and encourage participation by minority and disadvantaged persons in technological innovation.</p>
<p><b>Program Project Grant (P01)</b></p>	<p><b>Program Project Grants</b> are more complex in scope and budget than the individual basic research (R01) grant. While R01s are awarded to support the work of one principal investigator who, with supporting staff, is addressing a scientific problem, program project grants are available to a group of several investigators with differing areas of expertise who wish to collaborate in research by pooling their talents and resources. Program project grants represent synergistic research programs that are designed to achieve results not attainable by investigators working independently. <i>Not all awarding components accept P01 applications.</i></p>
<p><b>Research Center Grant (P50/P60)</b></p>	<p><b>Research Center Grants</b> serve varying scientific and IC-specific purposes, but they have elements in common. The grants are multidisciplinary in scope and may focus more on an area or discipline of science than on a specific theme or goal. Independent investigators direct the projects and cores. Center grants offer a greater opportunity for scientific interactions and overall progress than with individually-funded projects. <i>Not all awarding components accept P50/P60 applications.</i></p>
<p><b>Scientific Meeting Support (R13)</b></p> <p><a href="http://grants.nih.gov/grants/funding/r13/index.htm">http://grants.nih.gov/grants/funding/r13/index.htm</a></p>	<p>NIH provides support for scientific meetings, conferences, and workshops that are relevant to its scientific mission. Any U.S. institution or organization, including an established scientific or professional society, is eligible to apply. For more information and guidelines, see <a href="http://grants.nih.gov/grants/guide/pa-files/PAR-03-176.html">http://grants.nih.gov/grants/guide/pa-files/PAR-03-176.html</a>. <i>Applicants must obtain IC approval prior to submission.</i></p>
<p><b>Research Grants to Foreign Institutions and International Organizations</b></p>	<p><a href="http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600260">http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600260</a>.</p>

Type (Mechanism)	Description
<b>Training, Fellowships and Career Development Programs</b>	
<b>NIH Institutional Ruth L. Kirschstein National Research Service Award (T32/T34/T35)</b> <a href="http://grants.nih.gov/grants/guide/pa-files/PA-00-103.html">http://grants.nih.gov/grants/guide/pa-files/PA-00-103.html</a>	These awards are made to domestic institutions that have the facilities and faculty to provide for research training programs in scientific specialties. Grant funds may be used for personnel, equipment, supplies, trainee stipends (both pre- and postdoctoral), and related costs. See <a href="#">Section IV. Institutional Ruth L. Kirschstein National Research Service Award.</a>
<b>Individual Ruth L. Kirschstein National Research Service Award Fellowships (NRSA: F30/F31/F32/F33)</b> <a href="http://grants.nih.gov/training/nrsa.htm">http://grants.nih.gov/training/nrsa.htm</a>	These fellowships are awarded to qualified individuals at the predoctoral, postdoctoral, or senior investigator level to pursue full-time research training in designated biomedical or behavioral science areas. <b>NRSA APPLICANTS MUST USE PHS 416-1 FORMS/INSTRUCTIONS</b> ( <a href="http://grants.nih.gov/grants/funding/416/phs416.htm">http://grants.nih.gov/grants/funding/416/phs416.htm</a> )
<b>Career Development Award (K Award)</b> <a href="http://grants.nih.gov/training/careerdevelopmentawards.htm">http://grants.nih.gov/training/careerdevelopmentawards.htm</a>	Among NIH components, several types of career development awards are available to research and academic institutions on behalf of scientists who require additional independent or mentored experience in a productive scientific environment in order to further develop their careers in independent biomedical or behavioral research. See <a href="#">Section III. Career Development Awards.</a>
<b>APPLICATIONS AVAILABLE FROM OTHER OFFICES</b>	
<b>International Research Fellowship Award Application (NIH 1541-1)</b>	Fogarty International Center (FIC) (301) 496-1653
<b>Nonresearch Training Grant Application (PHS 6025)</b>	Health Resources and Services Administration (HRSA) (301) 443-6960
<b>Health Services Project Application (5161-1)</b>	Substance Abuse and Mental Health Services Administration (SAMHSA) (301) 436-8451

## **B. Mail Addressed to the National Institutes of Health**

All United States Postal Service (USPS) mail addressed to the National Institutes of Health must use the unique NIH zip code 20892. All USPS mail addressed to the National Library of Medicine should use the unique NLM zip code of 20894. All mail using 20892 and 20894 zip codes will be cleared through the NIH North Stonestreet Mail Facility. This will ensure that special procedures and precautions will be used to screen the mail before it is delivered to the various NIH offices on and off campus. This

is an important measure to provide for the safety of all individuals who must handle mail.

This procedure does not apply to courier deliveries (i.e. FEDEX, UPS, DHL, etc.) for the receipt of grant applications addressed to the Center for Scientific Review. The zip code for these deliveries is 20817. All applications and other deliveries to the Center for Scientific Review must either come via courier delivery or the USPS.

**NIH WILL NO LONGER ACCEPT APPLICATIONS DELIVERED BY INDIVIDUALS TO THE CENTER FOR**

SCIENTIFIC REVIEW. This restriction does not apply to USPS or courier delivery personnel.

Mail addressed to NIEHS in North Carolina should continue to show zip code 27709.

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### **C. Government Use of Information Under Privacy Act**

The Privacy Act of 1974 (5 U.S.C. 552a) is a records management statute and regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, the PHS is required to provide the following notification to each individual whom it asks to supply information.

The PHS maintains applications and grant records pursuant to its statutory authority for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of PHS programs. Provision of information is voluntary; however, a lack of sufficient information may hinder the ability of the PHS to review applications, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within the Department of Health and Human Services and outside the agency to the public, as required by the Freedom of Information Act and the associated DHHS regulations (45 CFR 5), including the Congress acting within its legislative authority, the National Archives, the General Accounting Office, the Bureau of Census, law enforcement agencies, and pursuant to a court order. Information also may be disclosed outside the Department, if necessary, for the following purposes:

1. To a Congressional office at the request of the record subject;
2. To the Department of Justice as required for litigation;
3. To the cognizant audit agency for auditing;
4. To qualified experts not within the definition of Department employees as prescribed in Department Regulations (45 CFR 5b.2) for

opinions as part of the application review/award process;

5. For an authorized research purpose under specified conditions;
6. To contractors for the purpose of processing, maintaining, and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;
7. To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and
8. To the applicant organization in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

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### **D. Information Available to the Principal Investigator**

Under the provisions of the Privacy Act, principal investigators may request copies of records pertaining to their grant applications from the PHS component responsible for funding decisions. Principal investigators are given the opportunity under established procedures to request that the records be amended if they believe they are inaccurate, untimely, incomplete, or irrelevant. If the PHS concurs, the records will be amended.

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### **E. Information Available to the General Public**

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee institution, the principal investigator, and the amount of the award. The description, on Form Page 2 of 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 the dissemination of scientific information and for scientific classification and program analysis purposes. These descriptions are available to the public from the NTIS.

NIH also routinely places information about awarded grants, including project title, name of the principal investigator, and project description (abstract) in the [CRISP](#) system.

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants upon request, regardless of the intended use of the information. Generally available for release, upon request are: all funded grant applications and progress reports **including** their derivative funded **noncompeting supplemental** grant progress reports; pending and funded **noncompeting continuation** progress reports; progress reports of grantees; and final reports of any review or evaluation of grantee performance conducted or caused to be conducted by the DHHS. Generally **not** available for release to the public are: **competing** grant progress reports (initial, competing continuation, and supplemental) for which awards have **not** been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups. Trade secrets and commercial, financial, or otherwise proprietary information may be withheld from disclosure. Information, which, if disclosed, would be a clearly unwarranted invasion of personal privacy, may also be withheld from disclosure. Although the grantee institution and the principal investigator will be consulted about any such release, the PHS will make the final

determination. If a requested document contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the balance of the document will be released.

## 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 provide, in response to a FOIA request, the research data first produced under the award. The term “research data” is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential to 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.