



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

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## **PART I**

### **Instructions for Preparing and Submitting an Application**



# 1. Foreword

The PHS 398 instructions contain information for preparing grant applications to the National Institutes of Health (NIH) and other Public Health Service agencies for:

- *Public Health Service (PHS) Research Grants*
- *Career Development Awards (K-awards)*
- *Institutional Research Training including Ruth L. Kirschstein National Research Service Awards (NRSA) (Training Grants)*

Applicants to PHS agencies other than NIH should contact the agency using the PHS Agency Contacts Table in 1.4 below because some awarding components have application requirements that differ from those for NIH.

NIH continues to transition grant mechanisms from the PHS 398 to the SF424 (R&R) and electronic submission through Grants.gov. This PHS 398 is required for all grant mechanisms that have not transitioned to the SF424 (R&R), including Resubmission, Renewal, Revision, and research training grants, changes of grantee institution, and cooperative agreement applications. Once a mechanism has transitioned to electronic submission the applicant must apply through Grants.gov using the SF424 (R&R) and electronic PHS 398 components that are provided as part of the electronic application forms.

For more information on NIH's transition plans, including a timeline for the transition of various mechanisms, see the website for Electronic Submission of Grant Applications:

<http://era.nih.gov/ElectronicReceipt/>.

Bookmark this website (<http://grants.nih.gov/grants/funding/phs398/phs398.html>) for easy electronic access to this document.

## Summary of Changes

These instructions include numerous clarifications and updates. The following table is a summary of policy changes and notifications implemented since the 04/2006 interim revision of the PHS 398 application.

TITLE	NIH GUIDE LINK
NIH Announces Plans to Eliminate Mailing of Paper Assignment and Change of Assignment Letters	NOTICE: NOT-OD-06-066 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-066.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-066.html</a>
NIH Policy on Late Submission of Grant Applications	NOTICE: NOT-OD-06-086 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-086.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-086.html</a>
Notice of New NIH Policy for Funding of Tuition, Fees, and Health Insurance on Ruth L. Kirschstein National Research Service Awards	Notice: NOT-OD-06-090 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-090.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-090.html</a>
Revision: Notice of New NIH Policy for Funding of Tuition, Fees, and Health Insurance on Ruth L. Kirschstein National Research Service Awards	NOTICE: NOT-OD-06-093 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-093.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-093.html</a>

TITLE	NIH GUIDE LINK
NIH Announces Requirement for Detailed (Non-Modular) Budget Submissions for All Competing Grant Applications from Foreign (Non-U.S.) Institutions	NOTICE: NOT-OD-06-096 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-096.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-096.html</a>
Change in Standing Receipt Dates for NIH/AHRQ/NIOSH Beginning in January 2007	NOTICE: NOT-OD-07-001 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-001.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-001.html</a>
Guidance to Applicant Organizations about Registering Research Fellows in the eRA Commons	NOTICE: NOT-OD-07-003 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-003.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-003.html</a>
Limits on Resubmission of an Application: Clarification of NIH Policy	NOTICE: NOT-OD-07-015 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-015.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-015.html</a>
Establishment of Multiple PI Awards for the Support of Team Science Projects	NOTICE: NOT-OD-07-017 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html</a>
New Limits on Appendix Materials for All NIH/AHRQ/NIOSH Grant Applications Beginning with Receipt Dates on or After January 3, 2007	NOTICE-OD-07-018 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html</a>
NIH Policy on Late Submission of Grant Applications - Clarification for Multiple PI Applications and New Submission/Receipt Dates	NOTICE-OD-07-026 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-026.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-026.html</a>
Change in Standing Receipt Dates for AIDS and AIDS-related applications for NIH/AHRQ Beginning in May 2007	NOTICE OD-07-053 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-053.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-053.html</a>
Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)	NOTICE OD-07-088 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html</a>
Implementation Guidance and Instructions for Applicants: Policy for Sharing of Data Obtained in NIH-Supported or Conducted Genome-Wide Association Studies (GWAS)	NOTICE OD-08-013 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html</a>
Clinical Trials Registration in ClinicalTrials.gov (Public Law 110-85): Competing Applications and Non-Competing Progress Reports	NOTICE OD-08-023 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html</a>

## Changes to instructions are highlighted as follows:

### Implementation of Grants.Gov Terminology

- As part of the ongoing effort to keep the PHS 398 and the SF424 (R&R) synchronized, new terminology is implemented throughout this document. For reference, the following table is provided:

OLD TERM	NEW TERM
Competing continuation application	Renewal application
Revision or amendment [to application]	Resubmission application
Competing supplement	Revision application
Principal Investigator	Program Director/Principal Investigator
Key Personnel	Senior/key Personnel
Performance site	Project/performance site
Duly authorized representative	Authorized Organizational Representative

### Definition of new investigator

- Revised to provide clarity.

### Structure of Document

- Instructions are reorganized for greater consistency with the SF424 (R&R) and PHS 398 Component Instructions used for electronic submission. A numerical reference system is incorporated in order to more closely parallel the SF424 (R&R) instructions. As a result there are some blank sections in this document labeled "Reserved."
- In Part I, the Research Plan is reorganized for consistency with the SF424 (R&R) instructions, with one exception: The section titled "Bibliography and References Cited" in the PHS 398 is requested in Section 5.5 Content of Research Plan, item 7.a; in the SF424 (R&R) this information is located in 4.4 Other Project Information component, as item 8.
- Part II is revised for purposes of clarity and ease of reference, and the definitions related to human subjects research are moved to Part III.

### Suggested Cover Letter Format

- A suggested cover letter format is provided for greater consistency and to facilitate the use of requests for specific Institutes or Centers (ICs) or Scientific Review Groups.

### Budget Justification

- The instructions for justification of a foreign applicant or foreign component are reworded for consistency with NIH criteria for funding a foreign project (i.e., the project must present special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental characteristics that augment existing U.S. resources) (see Part I, 4.5).

### Indefinite Plans for Involvement of Human Subjects or Use of Vertebrate Animals

- Instructions for the Research Plan sections addressing human subjects and vertebrate animals are modified to provide guidance to applicants when plans are indefinite at the time of application.

#### Instructions for Career Development Award Applications

- Term *mentor* is used in place of *sponsor*.
- Numerous instructional clarifications.

#### Institutional Research Training Application Including Ruth L. Kirschstein-NRSA Applications

- Instructions and forms are renamed to acknowledge that there are institutional training programs that are not Ruth L. Kirschstein National Research Service Awards.
- Integration of the NIH diversity recruitment and retention policy described in institutional Kirschstein-NRSA training grant, institutional career development, and research education Funding Opportunity Announcements (e.g., [PA-06-468](#)).
- Narrative instructions for training data tables are replaced with fillable format tables and examples of completed tables (see Form and Format changes below).
- Provision for multiple PD/PIs is included for institutional training grants.

#### Appendix Format

- Appendix material is to be submitted on CDs in PDF format, and will no longer be accepted on paper.

#### Part II, Instructions for Preparing the Protection of Human Subjects Section of the Research Plan

- All exemptions appear in one scenario (Scenario C).
- A scenario for "Delayed Onset of Human Subjects Research" is incorporated.

#### **Changes to specific form and format pages are noted below:**

##### 398 Face Page

- Item 3 changed from PI/PD to PD/PI to be consistent with SF 424(R&R).
- IACUC approval date (formerly item 5a) deleted since information is collected only as Just-in-Time; Item 5b renumbered 5a.

##### 398 Form Page 2 and Project/Performance Site Format Page

- Form page 2 is revised, and the Project/Performance Site Format Page created to collect information for each project/performance site as required by the Federal Financial Accountability and Transparency Act.

##### Modular Budget Form Page

- Form page is no longer included since mechanisms using modular budgets have transitioned to SF424 (R&R) and do not use the PHS 398 paper application. Modular budget form pages still exist as part of electronic submission.

##### Checklist Form Page

- A Disclosure Permission Statement checkbox is added to allow disclosure of certain information to organizations that may be interested in possible collaboration, investment, etc.

##### Institutional Training Grant Data Tables

- Fillable format pages and samples of completed tables provided to afford structure for and promote consistency in data.

## Important Reminders for all Applicants

Font and margin specifications must be followed; if not, application processing may be delayed or the application may be returned to the applicant without review. NIH requires the use of one of four approved fonts and a font size of 11 points or larger. The approved font options include two serif fonts (Palatino and Georgia) and two sans serif fonts (Arial and Helvetica). A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies. A smaller font size may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes, but this type must follow the font typeface requirement and be readily legible.

Prepare a *succinct* Research Plan. There is no requirement for applicants to use the maximum allowable pages allotted to the Research Plan (Part I, 5.5, Items 2-5). The remaining sections of the Research Plan (6-17) have no maximum allowable pages, but should also be succinct.

Several elements of an application are not required at the time the application is submitted. This information is requested later in the review cycle (i.e., just-in-time) to ensure that it is current. See [Just-In-Time Policy](#) in Part III. 1.7.

## 1.1 Application Guide Format

This edition of the PHS 398 is organized into three parts, and is available in two different formats: MS Word and PDF. Within each Part are links to pertinent sections of the application, other documents, or NIH web pages. To use these links in the MS Word version effectively, you must enable the "web" tool bar in order to have a "back button" to return to a page after using a link. The three parts of the 398 are described below:

### Part I: Instructions for Preparing and Submitting an Application

Part I includes instructions on submitting a grant application, completing the PHS 398 forms and format pages, preparing the cover letter, Research Plan, and checklist, and information on the peer review process. Section 7 of Part I provides instructions to prepare an individual Career Development Award application. Section 8 consists of instructions to prepare an institutional research training (including Ruth L. Kirschstein National Research Service Award) application.

### Part II: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan

Part II includes instructions for research that proposes to involve [human subjects](#), including scenarios and detailed instructions to complete [Items 8-11 of the Research Plan \(Human Subjects Research\)](#).

### Part III: Policies, Assurances, Definitions and Other Information

Part III includes information on policies, assurances, definitions, and other information relating to submitting applications to the PHS. Applicants should refer to this document as well as the PHS 398 instructional materials, [Grants Information](#) (GrantsInfo), and the relevant Grants Policy Statement for additional sources of information. The [NIH Grants Policy Statement](#) applies to all NIH awardees; other PHS agencies use the [HHS Grants Policy Statement](#).

Form pages are available **separately** on the NIH website (<http://grants.nih.gov/grants/funding/phs398/phs398.html#forms>).

**THESE INSTRUCTIONS AND APPLICATION FORMS (Revised 11/2007) SUPERSEDE ALL PREVIOUS EDITIONS.** Carefully read the instructions. Submission of an application that fails to meet the PHS requirements will be grounds for the PHS to delay the review or to return the application without peer review. A properly prepared application will facilitate the administrative processing and peer review that must occur before an award can be made.

While the instructions are generally applicable, grant programs of PHS agencies other than NIH may have additional specific instructions. Applicants should contact an official listed in the [table](#) of PHS agencies to obtain the most current information and instructions.

## 1.2 NIH Extramural Research and Research Training Programs

The NIH Office of Extramural Research is the focal point for policies and guidelines for extramural research grants administration (<http://grants.nih.gov/grants/oer.htm>).

The Division of Extramural Outreach and Information Resources (DEOIR) is the central source for general information about NIH extramural research and research training programs, funding mechanisms, the peer review system, and application procedures. Grants Information (GrantsInfo) may be contacted by e-mailing [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov), or calling (301) 435-0714.

## 1.3 Research Grant Mechanisms and Program Guidelines

A partial list of research grant mechanisms that use the paper PHS 398 Grant Application is provided below, however, not all awarding components use all programs. For a complete listing of program guidelines, visit the OER Grants website [http://grants.nih.gov/grants/funding/funding\\_program.htm](http://grants.nih.gov/grants/funding/funding_program.htm). As grant mechanisms transition to electronic submission through Grants.gov using the SF 424 (R&R) they will no longer use this paper PHS 398 application. See [http://era.nih.gov/ElectronicReceipt/strategy\\_timeline.htm](http://era.nih.gov/ElectronicReceipt/strategy_timeline.htm) for the latest information on the transition to electronic submission.

### Research Program Projects and Centers:

- [Program Project Grant \(P01\)](#)
- Exploratory Grants (P20)
- Center Core Grants (P30)
- Biotechnology Resource Grants (P41)
- [Research Center Grant \(P50\)](#)
- Comprehensive Center (P60)

### Training, Fellowships and Career Development Programs

- [NIH Institutional Ruth L. Kirschstein National Research Service Award \(T32\)](#)
- [Individual Ruth L. Kirschstein National Research Service Award Fellowships \(NRSA\) \(F31, F32, F33, F34, etc.\)](#)
- [Research Career Development Award \(K Award\)](#)

### Other Grant Mechanisms

- International Training Grants (D43, D71)
- Research Centers in Minority Institutions (G12)
- Resource-Related Research Projects (R24, U24)

## 1.4 Interactions with PHS Staff

The PHS agencies encourage applicants to communicate with staff throughout the entire application, review and award process. Web site addresses and phone numbers of relevant NIH awarding

components and other PHS agencies are listed in the table below. The non-NIH agencies listed below use this application form, but some have application requirements that differ from NIH. For specific instructions for AHRQ, CDC, FDA and IHS, refer to the links provided below and the terms and conditions of the Notice of Award.

All inquiries regarding the assignment, review, or recommendation on funding of applications are to be made only to PHS officials.

## PHS Agency Contacts

PHS AGENCY (LINK TO WEB SITE)	AWARDING COMPONENT (LINK TO WEB SITE)	TELEPHONE NUMBER
<a href="#">NATIONAL INSTITUTES OF HEALTH (NIH)</a>	<a href="#">Eunice Kennedy Shriver National Institute of Child Health and Human Development</a>	301-496-0104
NIH	<a href="#">Fogarty International Center</a>	301-496-1653
NIH	<a href="#">National Cancer Institute</a>	301-496-3428
NIH	<a href="#">National Center for Complementary and Alternative Medicine</a>	301-496-4792
NIH	<a href="#">National Center on Minority Health and Health Disparities</a>	301-402-1366
NIH	<a href="#">National Center for Research Resources</a>	301-496-6023
NIH	<a href="#">National Eye Institute</a>	301-451-2020
NIH	<a href="#">National Heart, Lung, and Blood Institute</a>	301-435-0260
NIH	<a href="#">National Human Genome Research Institute</a>	301-496-7531
NIH	<a href="#">National Institute on Aging</a>	301-496-9322
NIH	<a href="#">National Institute on Alcohol Abuse and Alcoholism</a>	301-443-4375
NIH	<a href="#">National Institute of Allergy and Infectious Diseases</a>	301-496-7291
NIH	<a href="#">National Institute of Arthritis and Musculoskeletal and Skin Diseases</a>	301-594-2463
NIH	<a href="#">National Institute of Biomedical Imaging and Bioengineering</a>	301-451-4792
NIH	<a href="#">National Institute on Deafness and Other Communication Disorders</a>	301-496-1804
NIH	<a href="#">National Institute of Dental and Craniofacial Research</a>	301-594-4800
NIH	<a href="#">National Institute of Diabetes and Digestive and Kidney Diseases</a>	301-594-8834
NIH	<a href="#">National Institute on Drug Abuse</a>	301-443-2755
NIH	<a href="#">National Institute of Environmental Health Sciences</a>	919-541-7723
NIH	<a href="#">National Institute of General Medical Sciences</a>	301-594-4499
NIH	<a href="#">National Institute of Mental Health</a>	301-443-3367
NIH	<a href="#">National Institute of Neurological Disorders and Stroke</a>	301-496-9248
NIH	<a href="#">National Institute of Nursing Research</a>	301-594-6906
NIH	<a href="#">National Library of Medicine</a>	301-496-4621

PHS AGENCY (LINK TO WEB SITE)	AWARDING COMPONENT (LINK TO WEB SITE)	TELEPHONE NUMBER
NIH	<a href="#">Center For Scientific Review</a>	301-435-0715
<a href="#">AGENCY FOR HEALTHCARE RESEARCH AND QUALITY</a>	<a href="#">Agency for Healthcare Research and Quality</a>	301-427-1447
<a href="#">CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)</a>	<a href="#">Coordinating Center for Health Information and Services</a>	404-498-1186
CDC	<a href="#">Coordinating Center for Infectious Disease</a>	404-639-3770
CDC	<a href="#">Coordinating Center for Environmental Health &amp; Injury Prevention</a>	770-488-4668
CDC	<a href="#">Coordinating Center for Health Promotion</a>	770-488-8390
CDC	<a href="#">Office of Public Health Research</a>	404-639-4621
CDC	<a href="#">National Institute for Occupational Safety and Health</a>	404-498-2530
CDC	<a href="#">Procurement and Grants Office</a>	770-488-2700
<a href="#">FOOD AND DRUG ADMINISTRATION</a>	<a href="#">Food and Drug Administration</a>	301-827-7185
<a href="#">INDIAN HEALTH SERVICE</a>	<a href="#">Indian Health Service</a>	301-443-0578
<a href="#">AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY</a>	<a href="#">Agency for Toxic Substances and Disease Registry</a>	404-842-6630
<a href="#">OFFICE OF PUBLIC HEALTH AND SCIENCE</a>	<a href="#">Office of Population Affairs</a>	301-594-4004
<a href="#">OFFICE OF PUBLIC HEALTH AND SCIENCE</a>	<a href="#">Office of Family Planning</a>	301-594-4008

## Before Submission

Applicants may contact NIH staff with a variety of questions before submitting an application.

- Contact GrantsInfo at (301) 435-0714 or email [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov), and/or the Division of Receipt and Referral in the Center for Scientific Review (CSR) at (301) 435-0715:
  - To identify Institutes/Centers (ICs) at NIH or other non-NIH agencies, and/or a Scientific Review Group (SRG), that might be appropriate for the application. Note that requests for assignment to an IC and/or a SRG may be made in a [cover letter](#) at the time of application submission.
  - To learn about [grant mechanisms](#).
  - To receive advice on preparing and submitting an application (e.g., format, structure).
- Contact program staff in the relevant awarding component:
  - To determine whether a proposed application topic would fit into the NIH IC or other non-NIH agency's programmatic area.
  - To learn about programmatic areas of interest to the IC or other non-NIH agencies.
  - To find out about requesting an assignment to an IC.
  - To discuss responding to a Request for Applications.



- Contact Scientific Review Officers (SRO) in the Center for Scientific Review to discuss requesting assignment to a SRG.

### **After Submission**

If the initial assignment to an IC or SRO seems inappropriate, the Program Director/Principal Investigator (PD/PI) may request reassignment. Such requests should be made in writing to:

Division of Receipt and Referral  
Center for Scientific Review  
National Institutes of Health  
6701 Rockledge Drive, Suite 2030, MSC 7720  
Bethesda, MD 20892-7720  
Fax requests (301-480-1987) are also acceptable.

Although these requests will be carefully considered, the final determination will be made by the PHS agency.

Applicants must never contact reviewers regarding their applications because discussion of the scientific content of an application or an attempt to influence review outcome will constitute a conflict of interest in the review process. Reviewers are required to notify the Scientific Review Officer if they are contacted by an applicant. Communication by the applicant to a reviewer may delay the review or result in the return of the application without review.

### **After Assignment**

Contact the SRO to discuss the review assignment, to request permission to send additional/corrective materials, and/or to discuss any review concerns (e.g., expertise needed on the study section, conflicts, reviewers that may have bias).

### **After Peer Review**

Feedback to applicants is very important. Once the PD/PI reviews the Summary Statement in the eRA Commons, the appropriate awarding component program official (noted in the Summary Statement) may be contacted:

- To discuss the review outcome of the application and obtain guidance.
- To get feedback and answers to any questions about the Summary Statement.
- To find out the meaning of a numerical designation pertaining to human subjects or vertebrate animals on the Summary Statement.
- To find out the funding status of an application.

The Peer Review Outcome Letter and Summary Statement will not be mailed to the PD/PI and may only be accessed through the eRA Commons.

## **1.5 Grants Policy Statements**

The [NIH Grants Policy Statement](#) serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of NIH awards.

The [HHS Grants Policy Statement](#) serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of grant awards from other PHS agencies, excluding NIH awards.

## 1.6 References

### Applicants New to NIH: Getting Started

[http://grants.nih.gov/grants/useful\\_links.htm](http://grants.nih.gov/grants/useful_links.htm)

### Award Data

<http://grants.nih.gov/grants/award/award.htm>

([CRISP](#), [extramural research grants](#), [award trends](#), [training and career awards](#))

### Contact Information for an NIH Staff Person

<http://ned.nih.gov>

NIH locator: (301) 496-4000

### eRA Commons

<https://commons.era.nih.gov/commons/index.jsp>

Institutions and Program Directors/Principal Investigators (PD/PIs) are required to register with the eRA Commons. Registered PD/PIs can check assignment/contact information, review outcome, and other important information.

Email the Commons Help Desk at [commons@od.nih.gov](mailto:commons@od.nih.gov).

Call the Commons Help Desk at 1-800-504-9552 (toll-free) or 301-402-7469; 301-451-5939 (TTY). Business hours are M-F 7am-8pm Eastern Time.

### Grant Writing Tips and Sample Applications

[http://grants.nih.gov/grants/grant\\_tips.htm](http://grants.nih.gov/grants/grant_tips.htm)

### Grants Information

<http://grants.nih.gov/grants/qiwelcome.htm>

E-mail: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)

Telephone: (301) 435-0714

### NIH Office of Extramural Research Human Subjects Website

<http://grants.nih.gov/grants/policy/hs/index.htm>

This site provides DHHS and NIH requirements and resources for the extramural community involved in human subjects research.

### Office of Biotechnology Activities (OBA)

<http://www4.od.nih.gov/oba>

NIH Guidelines for Research Involving Recombinant DNA Molecules and Institutional Biosafety Committee Registration

Telephone: (301) 496-9838

### Office of Human Research Protections (Department of Health and Human Services)

<http://www.hhs.gov/ohrp>

Information about human subject protections, Institutional Review Boards, and Federal Wide Assurances.

Telephone: 1-866-447-4777 or (301) 496-7005

### **Office of Laboratory Animal Welfare (OLAW)**

<http://grants.nih.gov/grants/olaw/olaw.htm>

Information about animal welfare policy requirements, Institutional Animal Care and Use Committees (IACUC), and Animal Welfare Assurances.

Telephone: (301) 496-7163

### **Receipt/Referral of an Application**

<http://www.csr.nih.gov/EVENTS/AssignmentProcess.htm>

Division of Receipt and Referral

Center for Scientific Review

Telephone: (301) 435-0715

Fax: (301) 480-1987

### **Specific Application: Before Review**

Telephone or e-mail the Scientific Review Officer identified for the application in the eRA Commons.

### **Specific Application: Post Review**

Telephone or e-mail the NIH Program Official named in the Summary Statement for the application.

## **1.7 Authorization**

The PHS requests the information described in these instructions pursuant to its statutory authorities for awarding grants, contained in Sections 301 (a) and 487 of the PHS Act, as amended (42 USC 241a and 42 USC 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the ability of the PHS to review an application and to monitor the grantee's performance.

## **1.8 Paperwork Burden**

The PHS estimates that it will take approximately 40 hours to complete this form. This estimate excludes time for development of the scientific plan. Other items such as human subjects are cleared and accounted for separately, and therefore are not part of the time estimate. An agency may not conduct or sponsor the collection of information unless it displays a currently valid OMB control number. Nor is a person required to respond to requests for the collection of information without this control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATT: PRA (0925-0001). Do not send applications or any materials related to training or career award applications to this address.

## 2. General Instructions

### 2.1 Introduction

Read all of the instructions thoroughly prior to application preparation.

These instructions pertain to applications for research project grants that have not transitioned to electronic submission using the SF424 (R&R). Use the additional instructions and sample pages included in [Section 7](#) of this Part when applying for Career Development Awards, and [Section 8](#) of this Part when applying for an Institutional Research Training grant (including Ruth L. Kirschstein National Research Service Awards).

For other specialized grants or cooperative agreements, request additional instructions from the appropriate NIH awarding component or other PHS agency. Phone numbers for contacting the appropriate staff are listed in the [Agency Contact Table](#). For further assistance, contact:

GrantsInfo  
National Institutes of Health (NIH)  
E-mail: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)  
Phone: (301) 435-0714

Read and follow the instructions carefully to avoid delays, misunderstandings and possible return of the application. Adherence to font and margin requirements is necessary for several reasons. No applicant should have an advantage over other applicants by providing more content using smaller, denser type. Small type sizes may also make it difficult for reviewers to read the application.

The NIH Center for Scientific Review (CSR), Division of Receipt and Referral, has the responsibility to make the final determination of legibility and the authority to return applications. This decision is final and not subject to appeal. Inquiries should be directed to the:

CSR, Division of Receipt and Referral  
Phone: 301-435-0715; TTY 301-451-0088; Fax: 301- 480-1987

## 2.2 Registration Processes

### 2.2.1 (Reserved)

### 2.2.2 DUNS Registration for the Applicant Organization & Subaward/Consortium Organizations

A Data Universal Numbering System (DUNS) number is required for all applications (paper and electronic) and must be obtained by the organization prior to submission. For organizations that already have multiple DUNS numbers, one DUNS number should be selected by an authorized organizational representative and used consistently for all application submissions. The authorized organizational representative should be consulted to determine the appropriate number to use for applications.

The DUNS number is considered the Federally-recognized unique identifier and is used for reporting purposes, particular those associated with the *Federal Financial Assistance Transparency Act (FFATA) of 2006* (P.L. 109-282).

FFATA also includes a requirement for reporting on subaward information. Therefore accurate DUNS for each subaward/consortium organization must also be provided as part of the Project/Performance Site information.

Additional information on DUNS registration is found at:  
<http://fedgov.dnb.com/webform/displayHomePage.do>

A DUNS number is required for Central Contractor Registration (see 2.2.3. below).

### 2.2.3 Central Contractor Registration (CCR) for the Applicant Organization

Prior to submission of all applications (paper and electronic), applicant organizations are required to be registered in the Central Contractor Registration (CCR). Organizations must maintain the currency of the information in the registry and renew the registration annually. A DUNS number is required for CCR registration.

CCR is a government-wide registry for organizations doing business with the U.S. Government. The registry collects, validates, stores, and disseminates data in support of agency acquisition missions, including Federal agency contract and assistance awards. The CCR registry will be used by Federal agencies to validate the DUNS number provided as part of the application process. Validation of the DUNS number will be critical for agencies to comply with the requirements of the *Federal Financial Assistance Transparency Act (FFATA) of 2006* (P.L. 109-282).

Organizational information entered into the CCR must match that in the eRA Commons. Since CCR Registration can take several days to complete, the process should be started well in advance of a submission date to avoid potential delays. An authorized organizational representative should be consulted to determine if the organization has properly completed and maintained CCR registration. Additional information on CCR registration is found at: <http://www.ccr.gov/>.

### 2.2.4 eRA Commons Registration

The applicant organization and the PD/PI must also complete a **one-time** registration in the eRA Commons. Access to the Commons is vital for all steps in the process after application submission. An organization and PD/PIs must be registered in the Commons for purposes of retrieval of grant information, institute/center assignments, review outcomes, and Summary Statements. Institutional/organizational officials are responsible for registering PD/PIs in the eRA Commons. PD/PIs should work with their authorized organizational official (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

**IMPORTANT:** The eRA Commons registration process should be started at least **two (2) weeks** prior to submission. A valid PD/PI Commons user name ID must be entered in item 3.h of the Face Page.

#### 2.2.4.1 Commons Registration for the Organization

Organizations may verify their current registration status by accessing the “List of Grantee Organizations Registered in NIH eRA Commons” ([http://era.nih.gov/userreports/ipf\\_com\\_org\\_list.cfm](http://era.nih.gov/userreports/ipf_com_org_list.cfm)).

To register an Organization in the eRA Commons:

1. Open the eRA Commons homepage (<https://commons.era.nih.gov/commons/>).
2. Click Grantee Organization Registration (found in “About the Commons” links on the right side of the screen).
3. Follow the step-by-step instructions. Remember to fax in the registration signature page to eRA.
4. Click Submit. The organization is registered when the NIH confirms the information and sends an email notification of registered Signing Official (SO) account (userid/password).

Organizational data elements, such as Institutional Profile Number (IPF), Entity Identification Number (e.g., 555555555A5) and DUNS Number must be accurately identified. **Note the DUNS number must be included in the Institutional Profile, and must match the number on the application.**

Since eRA has not required a DUNS number during eRA Commons registration, there are many accounts that do not contain valid information in this field. Prior to submission, the Authorized Organizational Representative/SO should verify that their organization's eRA Commons profile contains the valid DUNS number that will be used for the submission process. The SO has the ability to edit this field in the organization profile in Commons.

To confirm that the organization has a DUNS number or to find out if the DUNS number you have matches the one in the Commons, access the List of Grantee Organizations Registered in NIH eRA Commons ([http://era.nih.gov/userreports/ipf\\_com\\_org\\_list.cfm](http://era.nih.gov/userreports/ipf_com_org_list.cfm)). This listing of grantee organizations registered in Commons and their DUNS numbers can be accessed without logging into Commons.

#### **2.2.4.2 Commons Registration for the Project Director/Principal Investigator (PD/PI)**

The individual designated as the PD/PI on the application must also be registered in the Commons. The PD/PI must hold a PI account **and** be affiliated with the applicant organization. **This registration must be done by an organizational official (or delegate) who is already registered in the Commons.** To register PD/Pis in the Commons, refer to the NIH eRA Commons System Users Guide ([http://era.nih.gov/Docs/COM\\_UGV2630.pdf](http://era.nih.gov/Docs/COM_UGV2630.pdf)).

Once the PD/PI has received email confirming his/her registration within the Commons, the PD/PI must verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. Please have the PD/PI review and update, as needed, data elements such as first name, middle initial, last name, prefix and/or suffix to PD/PI name (including all embedded punctuation), email, phone, fax, street address, city, state, country, zip and degrees earned. These data must contain the most recent information in order for the application to be processed accurately.

Both PD/PI and SO need separate accounts in Commons since both must verify the application. If you are the SO for your organization as well as a PI of the grant, you will need two separate accounts with different user names – one with SO authority and one with PI authority. When an organization is registered, an SO account is created. Log on to the account with the SO authority role and create another account with PI authority.

It is important to note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

## **2.3 (Reserved)**

## **2.4 Funding Opportunities**

Grants for health-related research and research training projects or activities make up the largest category of funding provided by the NIH Institutes/Centers (ICs) and other non-NIH agencies. Most applications for support are **unsolicited** and originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the NIH. Research project grants are awarded to organizations/institutions on behalf of PD/Pis to facilitate the pursuit of a scientific objective when the idea for the research is initiated by the investigator. If the funding agency anticipates substantial program involvement during the conduct of the research, a cooperative agreement will be awarded, rather than a grant. The NIH awards grants and cooperative agreements for terms ranging from one to five years. Organizational/institutional sponsorship assures that the

awardee organization will provide the facilities and the financial stability necessary to conduct the research, and be accountable for the funds. For a list and brief description of grant mechanisms, [see Part III, 4.1.](#)

## 2.4.1 NIH Guide for Grants and Contracts

The [NIH Guide for Grants and Contracts](#), a weekly electronic publication (<http://grants.nih.gov/grants/guide>), contains announcements about funding opportunities, such as Requests for Applications (RFAs) and Program Announcements (PAs), including Parent Announcements, from NIH and other PHS agencies. The *NIH Guide* also contains vital information about policies and procedures. To subscribe to the *NIH Guide*, visit <http://grants.nih.gov/grants/guide/listserv.htm>.

## 2.4.2 Funding Opportunity Announcements (FOAs)

To hasten the development of a program or to stimulate submission of applications in an area of high priority or special concern, an awarding component will encourage applications through the issuance of a PA to describe new, continuing, or expanded program interests, or issuance of an RFA inviting applications in a well-defined scientific area to accomplish a scientific purpose.

Definitions are as follows:

**Parent Announcements:** Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA). For applicants who wish to submit what were formerly termed “investigator-initiated” or “unsolicited” applications, NIH and other PHS agencies have developed Parent Announcements. Responding to such an omnibus or umbrella Parent FOA ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. Additional information about, as well as links to published Parent Announcements, can be found at: [http://grants.nih.gov/grants/guide/parent\\_announcements.htm](http://grants.nih.gov/grants/guide/parent_announcements.htm).

**Program Announcement (PA):** A formal statement about a new or ongoing extramural activity or mechanism. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or mechanism, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time.

**Request for Applications (RFA):** A formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application submission date(s). Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

PAs (including Parent Announcements) and RFAs are published in the [NIH Guide for Grants and Contracts](#) (<http://grants.nih.gov/grants/guide>), the [Federal Register](#) (<http://www.gpoaccess.gov/nara/index.html>), and on Grants.gov under Find Grant Opportunities ([http://www.grants.gov/applicants/find\\_grant\\_opportunities.jsp](http://www.grants.gov/applicants/find_grant_opportunities.jsp)). Read the announcement carefully for special instructions. The instructions in the announcement may differ from these general instructions, and the instructions in the announcement **always** supersede these general instructions. Each announcement published in the [NIH Guide for Grants and Contracts](#), the [Federal Register](#), [Grants.gov Find](#), or other public document contains contact information under *Inquiries* in addition to information specific to the announcement.

While individual announcements will continue to carry an announcement number reference to “PA” or “RFA”, all announcements are “Funding Opportunity Announcements (FOAs).” This general term will be used to reference any type of funding announcement. NIH will continue to use the PA and RFA

references in the actual announcement number to distinguish between the various types of announcements.

## **2.5 (Reserved)**

## **2.6 Format Specifications**

Follow font and format specifications. Otherwise, application processing may be delayed, or the application may be returned to the applicant without review.

### **Font**

- Use an *Arial, Helvetica, Palatino Linotype or Georgia* typeface, a black font color, and a font size of 11 points or larger. A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.
- Use black ink that can be clearly copied.
- Print must be clear and legible.

### **Paper Size and Page Margins**

- Use *standard size (8 ½" x 11")* sheets of paper.
- Use at least one-half inch margins (top, bottom, left, and right) for all pages, including continuation pages. No information should appear in the margins, including the PD/PI's name and page numbers.

### **Page Formatting**

- Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.
- The application must be single-sided and single-spaced.
- Consecutively number pages throughout the application. Do not use suffixes (e.g., 5a, 5b).
- Do not include additional pages between the face page and page 2.
- Do not include unnumbered pages.

### **Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes**

- A smaller type size is acceptable, but it must be in black ink, readily legible, and follow the font typeface requirement.

### **Grantsmanship**

- Use English and avoid jargon.
- If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

### **Photographs and Images**



- Do not include photographs or other materials that are not printed directly on an application page in the body of the application. Pictures or other materials that are glued or taped onto application pages are incompatible with the current duplication/scanning process.
- You may include black-and-white or color images in the six (6) submitted copies provided such images are printed directly on the application page and are critical to the content of the application.

## Copies

- Send the original application (signed by an authorized organizational official) and five identical, legible, single-sided photocopies.
- Do not use photo reduction.
- The application must contain only material that reproduces well when photocopied in black and white. Glossy photographs or other materials that cannot be photocopied must be submitted in the appendix (see [Section 5.7](#)). *Note:* Photographs may be included in the appendix; however, a photo copy of each must also be included within the page limitations of the Research Plan.

## Page Limitations and Content Requirements

All applications and proposals for NIH funding must be self-contained within specified page limitations.

Observe the page number limitations given in the [table](#) below. Only in cases involving interdependent multiple subprojects (e.g., Program Projects and Multi-Center Clinical Trials) will the PHS accept applications that exceed the page number limitations. However, specific page number limits may apply to each subproject. For information pertaining to page number limits for such projects, contact the awarding component to which the application may be assigned. (See [Agency Contact Table](#).) The page number limitations may also be different for other specialized grant applications; consult and follow the additional instructions for those applications.

SECTION	PAGE LIMIT <sup>1</sup>	CONTENT
Biographical Sketches	4 pages per person.	No more than 4 pages for each Senior/Key Personnel and each Other Significant Contributor.
Research Plan <sup>2</sup> Section 1	New application - not allowed. Resubmission application - 3 pages. Revision application - 1 page.	See Instructions.
Research Plan Sections 2 – 5	25 pages.	Limit includes text, and all figures, tables and diagrams.
Research Plan Sections 6 – 17	None.	See Instructions.
Appendix	No page limitations, but limit on number of items (no more than 3 publications).	See Instructions. Limited publications allowed. Photographs and other images must also be included in the Research Plan.

<sup>1</sup> Page limitations specified in the Funding Opportunity Announcements (FOAs) published in the Guide always supersede these instructions.

<sup>2</sup> See Section 5.5 for more information on the content of the Research Plan.

## 2.7 Resubmission Applications

For all original new (i.e., never submitted) and competing renewal applications submitted for the January 25, 2009 due date and beyond, NIH will accept only a single amendment (A1) to the original application (called a resubmission application). There is no time limit for a resubmission application. Any second resubmission will be administratively withdrawn and not accepted for review. For original new and competing applications submitted prior to January 25, 2009, applicants are permitted two resubmissions (A1 and A2). For these “grandfathered” applications, any second resubmission (A2) must be submitted no later than January 7, 2011, and NIH will not accept any A2 resubmissions after that date. See [NIH Policy on Resubmission Applications](#) in Part III, 1.3.

NIH has established policies for application resubmissions of certain categories. See [Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code](#) in Part III, 1.2.

There are four requirements for a Resubmission application:

- The Summary Statement must be available in the eRA Commons (<http://commons.era.nih.gov/commons/>).
- The PD/PI(s) must make significant changes to the application.
- An Introduction must be included that summarizes the substantial additions, deletions and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. The Introduction is separate from the Cover Letter and should be placed immediately before item 2. of the Research Plan. Page limits for the Introduction **should not exceed three pages unless the FOA specifies otherwise.**
- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or change of typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Preliminary Studies/Progress Report section (see 5.5, item 4) should incorporate work completed since the prior version of the application was submitted.

See [NOT-OD-07-083](#) for special conditions and due dates for new investigator resubmission applications submitted for consecutive review cycles. Note this applies only to new investigator R01s submitted for standard receipt dates and reviewed in recurring study sections in CSR.

Acceptance of a resubmission application will not automatically withdraw the prior version. eRA keeps all versions (e.g., 01, A1) of a grant application active and provides an internal Multiple Active Applications (MAA) flag for each application in an active cluster. The cluster allows applicants to identify quickly all versions of one application. If any version in a cluster is awarded, all other applications within the cluster will be automatically withdrawn without any additional action by applicants or staff.

Investigators who have submitted three versions of an application and have not been successful often ask NIH what constitutes 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 Resubmission application. Simply rewording the title and 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. Requests for review by a different review committee or funding consideration by a different NIH IC are not sufficient reasons to consider an application as new.

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. If identified after assignment or review, identical applications will be withdrawn.

## 2.8 Revision Application

A Revision application (formerly called a competing supplement) may be submitted to request support for a significant expansion of a project's scope or research protocol. Revision applications are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. **A Revision application must not be submitted until after the original application has been awarded and may not extend beyond the term of the current award period.**

**Introduction:** Provide a one-page introduction at the beginning of the Research Plan that describes the nature of the revision and how it will influence the Specific Aims, Research Design, and Methods of the current grant. Any budgetary changes for the remainder of the project period of the current grant should be discussed under the budget justification. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed revision in relation to the goals of the original application.

If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the SRG, then the applicant must respond to the criticisms in the prior Summary Statement, and substantial changes must be clearly evident and summarized in the Introduction.

### Administrative Supplements

An administrative supplement provides additional funding to meet increased costs that are within the scope of an approved application, but that were unforeseen when the new or competing Renewal application was submitted. If considering administrative supplemental funding, consult in advance with the designated Grants Management Officer and Program Official. It is important to submit a request before the grant expires. To be considered for an administrative supplement, submit a request in writing to the Institute/Center, **not** to the Division of Receipt and Referral, Center for Scientific Review. The request must be signed by the authorized Business Official and describe the need for additional funding and the categorical costs. In the letter, point out what will NOT be accomplished if such a request is denied. Administrative supplements are **not** submitted using the 398 Application.

## 2.9 Similar, Essentially Identical, or Identical Applications

Submissions of identical applications to one or more components of the PHS are not allowed, and the NIH will **not** accept similar grant applications with essentially the same research focus from the same applicant organization. This includes derivative or multiple applications that propose to develop a single product, process or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical grant applications submitted by different applicant organizations will not be accepted. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used elsewhere in the preparation and submission of a similar grant application. Applications to the NIH are grouped by scientific discipline for review by individual Scientific Review Groups and not by disease or disease state. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed or the application(s) may be returned to the applicant without review.

Essentially identical applications will only be reviewed in the following circumstances: 1) an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for a research project; and 2) an application for a research project identical to a subproject of a program project or center grant application.

## 2.10 (Reserved)

## 2.11 (Reserved)

## 2.12 (Reserved)

## 2.13 Submission of Supplementary or Corrective Information

Unless specifically required by these instructions, do not send supplementary or corrective material after the submission date unless the Scientific Review Officer of the Scientific Review Group solicits or agrees to accept this information.

## 2.14 Application Submission Dates

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

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

**Weekend/Federal holiday submission dates.** If a submission date falls on a weekend, it will be extended to the following Monday; any time the date falls on a Federal holiday the submission date will be extended to the following business day. The application will be on time if it is sent on or before the following business day.

**Funding Opportunity Announcements (RFAs and PARs). Applications in response to announcements with special receipt dates must be received at NIH by the specified date.** However, an application received after the deadline may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier not later than 1 week prior to the deadline date. Note that this differs from the procedures for submitting applications for the standard due dates, which are considered submission or “send by” dates.

**Late applications.** Permission is **not** granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a cover letter explaining the reasons for the delay **must** be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral in advance will not influence the acceptance of a late

application. For additional information on late applications, see NIH Guide Notices [OD-06-086](#) and [OD-07-026](#).

## 2.15 Submission, Review and Award Cycles

The PHS submission, review, and award schedule is provided at this website:

<http://grants.nih.gov/grants/dates.htm>. Note that many funding mechanisms have transitioned to electronic submission and the SF424 (R&R) application and instructions. The PHS 398 should only be used for those mechanisms where the Application Form is identified as PHS 398. Applicants should refer to the OER Electronic Submission of Grant Applications website, <http://era.nih.gov/ElectronicReceipt/> for details on the transition to electronic submission.

For specialized grant applications, consult with the appropriate PHS agency prior to the preparation of an application.

### Application Assignment Information

Competing grant applications submitted to the PHS agencies will be processed through the Division of Receipt and Referral, CSR, unless otherwise stated. Administrative information about the application is entered into a computer system. The application will be assigned to an appropriate Scientific Review Group and awarding component. Assignment is based on the scientific content of the application using established referral guidelines.

After the submission date, usually within 2 weeks, the following information regarding the grant application will be available in the NIH eRA Commons for viewing by the PD/PI(s) and an authorized organizational official:

- application assignment number;
- name, address, and telephone number of the Scientific Review Officer of the Scientific Review Group to which the application has been assigned for peer review; and
- assigned Institute/Center information.

If assignment information is not available in the eRA Commons within two weeks of the submission date, contact the Division of Receipt and Referral, Center for Scientific Review (CSR), National Institutes of Health, Bethesda, MD 20892-7720, (301) 435-0715. If there is a change in assignment, you will receive a notification and the change will be reflected in the eRA Commons.

Applicants must **not** communicate directly with any review group member about an application either before or after the review. Failure to strictly observe this policy will create serious breaches of confidentiality and conflicts-of-interest in the peer review process. From the time of assignment to the time the review of the application is complete, applicant investigators must direct all questions to the Scientific Review Officer. This individual is in charge of the review group and is identified in the eRA Commons.

## 2.16 Resources for Finding Help

### 2.16.1 (Reserved)

### 2.16.2 Finding Help for the eRA Commons Registration

If help is needed with the eRA Commons registration process for the applicant organization and PD/Pis, contact the eRA Commons Helpdesk:

eRA Commons Helpdesk: <http://ithelpdesk.nih.gov/eRA/>

eRA Commons Helpdesk Email: [commons@od.nih.gov](mailto:commons@od.nih.gov)

eRA Commons Phone: 301-402-7469  
866-504-9552 (Toll Free)  
301-451-5939 (TTY)

The eRA Commons Helpdesk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time.

### 2.16.3 Finding Help for Application Preparation

If after reviewing these application instructions, help is needed in preparing the application, contact GrantsInfo:

GrantsInfo Phone: 301-435-0714  
301-451-0088 (TTY)

GrantsInfo Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)

## 3. Submission of the Grant Application

**Submit a complete application.** Incomplete applications will be grounds for the PHS to return the application without peer review. An application will be returned if it is illegible, if the instructions were not followed, or if the material presented is insufficient to permit an adequate review.

The application must be complete and accurate at the time of submission. There is no guarantee that the Scientific Review Officer will accept or the peer reviewers will consider late material.

### 3.1 Cover Letter

Applicants are encouraged to include a cover letter with the application. The letter is only for internal agency use and will not be shared with peer reviewers. Place the letter at the beginning of the original application; do not copy it.

- Application title.
- Funding Opportunity Announcement (PA, RFA or Parent Announcement title, if applicable).
- Request of an assignment (referral) to a particular IC or [Scientific Review Group \(SRG\)](#). While requests are given careful consideration, the PHS makes the final determination for assignments. (See suggested format below.)
- List of individuals (e.g., competitors) who should not review the application and why.
- Disciplines involved, if multidisciplinary.
- Statement that any required NIH approval documentation for the type of application submitted is enclosed. This may include approval for applications requesting \$500,000 or more, approval for Conference Grant, Cooperative Agreement, etc.
- For late applications (see [Late Application Policy](#)), include an explanation of the delay as part of the cover letter.

#### Suggested Cover Letter Format

The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to ICs and to scientific review groups (SRGs). DRR will be utilizing knowledge

management approaches as an adjunct to the work of referral experts as part of an overall plan to shorten the time from submission to review. Analysis has shown that requests made by investigators are a valuable source of information in this process. In order to facilitate the use of these requests in conjunction with knowledge management analysis of the content of the application, applicants are requested to use the following format when assignment requests are contained in a cover letter.

- List one request per line.
- Place institute/center (IC) and SRG review requests (if both are made) on separate lines.
- Place positive and negative requests (if both are made) on separate lines.
- Include name of IC or SRG, followed by a dash and the acronym. Do not use parentheses.
- Provide explanations for each request in a separate paragraph.

Examples:

Please assign this application to the following:

Institutes/Centers

National Cancer Institute - NCI

National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC

Cancer Etiology Study Section – CE

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

The reasons for this request are [provide a narrative explanation for the request(s)].

## 3.2 Number of Copies

Submit the **original and five** identical, legible, single-sided photocopies of each application. The **original must be signed** by an authorized organizational official.

## 3.3 Bindings and Packaging

Submit the following materials in *one* package:

- cover letter (original only);
- original application, including the Personal Data page at the end of the application;
- five copies of the application, made after the original has been signed and **not** including the Personal Data Page;
- Appendix materials – five identical CDs of all appendix material in PDF format.

Do not include more than one application (original plus 5 copies and appendices) in each mailing envelope.

**Cover letter.** Place the original cover letter at the beginning of the original application. It should not be duplicated.

**The original application.** The original application must be single-sided, with the required signature on the Face Page. Do **not** staple or otherwise bind the original application. Rubber bands or clips are acceptable. Assemble the pages in the order specified in the table of contents. Place the Personal Data page at the end of the application; it is **not** to be duplicated.

**Five identical, single-sided copies of the original application.** Make the copies **after** an authorized organizational official has signed the Face Page so that the official's signature is present on the copies. Do **not** include the cover letter or the Personal Data Page in the copies. Do not staple or otherwise bind the five copies of the original application. Rubber bands or clips are acceptable.

**Five identical CDs containing all appendix material.** When preparing CDs:

- Use PDF format.
- Label each disk with the PD/PI name and application title.
- If burning CD-ROM disks on a Mac, select the ISO 9660 format.
- Do not use compression techniques for the electronic files.
- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

### 3.4 Application Mailing Address

For applications to NIH, use the mailing labels provided at the end of the forms.

Send the application to the following address, making sure to use the correct ZIP code:

Center for Scientific Review  
National Institutes of Health  
6701 Rockledge Drive, Suite 1040  
MSC 7710  
Bethesda, MD 20892-7710  
**(United States Postal Service (USPS) Express or Regular mail)**  
or  
Bethesda, MD 20817 **(Express/Courier Non-USPS Service)**

**C.O.D. applications will not be accepted.**

All applications and other deliveries to the Center for Scientific Review must come either via courier delivery (e.g., Federal Express, DHL, UPS) or via the USPS. Applications delivered by individuals to the Center for Scientific Review will not be accepted. For additional information, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html>.

There may be additional instructions for submission of responses to RFAs; check the FOA for details.

For applications to other (non-NIH) PHS agencies, refer to the FOA for submission instructions and mailing addresses.

## 4. Completing the PHS 398 Forms and Format Pages

Prepare the application using the PHS 398 MS WORD or PDF form pages and format pages as provided at <http://grants.nih.gov/grants/funding/phs398/phs398.html>.



- *Form pages* must be identical to those provided. You may substitute computer-generated facsimiles for government-provided forms; however, they must maintain the exact wording and format of the government forms, including all captions and spacing.
- *Format pages* are intended to assist you in the development of specific sections of the application. Alternatively, you may create a page similar to any format provided as long as all the requisite information is included.
- Shading/colors may not be used in any text portions, including the face page.
- Font sizes on some PHS 398 form pages vary due to field or space limitations. The PHS 398 Microsoft Word (MS Word) and Portable Document File (PDF) Form Pages as provided are acceptable to NIH. All other sections of the application (e.g., Biographical Sketch; Introduction, if necessary; and the Research Plan) must conform to the font requirements stated below.
- Some fields on the PDF Form Pages are pre-set to auto calculate. In these cases, a zero will appear until actual data are entered.

## 4.1 Face Page

The first part of the Face Page ([Form Page 1](#)) must be printed on a single page. The Face Page must not have any shading or colors. Form Page 1-continued is only for multi-PD/PI applications; if used, it should be printed as a separate page.

The information provided on the Face Page of the application and the fiscal information, including the calculation of F&A costs, must be verified by the official signing for the applicant organization.

### Item 1. Title of Project

**Do not exceed 81 characters, including the spaces between words and punctuation.** Choose a descriptive title that is specifically appropriate. A new application must have a different title from any other PHS project with the same PD/PI. A Renewal or Resubmission application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title. A Revision application **must** have the same title as the currently funded grant.

### Item 2. Response to Specific Request for Applications (RFA) or Program Announcement (PA)

Check “Yes” and insert the appropriate announcement number (e.g., PA-06-512) and title of the announcement if the application is submitted in response to an RFA or a PA issued through the NIH Guide for Grants and Contracts.

### Item 3. Program Director(s)/Principal Investigator(s) (PD/PI)

**New Investigator.** Check “Yes” in the “New Investigator” box only if the PD/PI has not previously competed successfully as PD/PI for a significant NIH independent research award. Specifically, a PD/PI is identified as a New Investigator if he/she has not previously competed successfully for an NIH-supported research project **other than** the following small or early stage research awards:

- Pathway to Independence Award-Research Phase (R00)
- Small Grant (R03)
- Academic Research Enhancement Award (R15)
- Exploratory/Developmental Grant (R21)
- Clinical Trial Planning Grant (R34)

- Dissertation Award (R36)
- Small Business Technology Transfer Grant-Phase I (R41)
- Small Business Innovation Research Grant-Phase I (R43)
- Shannon Award (R55)
- NIH High Priority, Short-Term Project Award (R56)
- Competitive Research Pilot Projects (SC2, SC3)

Additionally, the PD/PI is not excluded from consideration as a “New Investigator” if he/she has received an award from any of the following classes of awards:

#### **Training-Related and Mentored Career Awards**

- All Fellowships (F awards)
- All career awards (K awards)
- Loan repayment contracts (L30, L32, L40, L50, L60)

#### **Instrumentation, Construction, Education, Health Disparity Endowment Grants, or Meeting Awards**

- G07, G08, G11, G13, G20
- S10, S15, S21, S22

**Note regarding grants with Multiple PD/PIs:** In the case of a grant application that involves more than one PI, all PD/PIs must meet the definition of New Investigator to check “Yes” in the “New Investigator” box.

#### **Item 3a. Name of Program Director/Principal Investigator (PD/PI)**

**Name of Program Director/Principal Investigator.** Name the one person responsible to the applicant organization for the scientific and technical direction of the project. **PHS staff conduct official business only with the named PD/PI and institutional officials.** A Revision application **must** have the same PD/PI as the currently funded grant.

When multiple PD/PIs are proposed, use the Face Page-Continued page to provide items 3a – 3h for all PD/PIs. NIH requires one PD/PI be designated as the “contact PD/PI” for all communications between the PD/PIs and the agency. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PD/PIs, but has no special roles or responsibilities within the project team beyond those mentioned above. The contact PD/PI may be changed during the project period. The contact PD/PI should be listed in block 3 of Form Page 1 (the Face Page), with all additional PD/PIs listed on Form Page 1-Continued. When inserting the name of the PD/PI in the header of each application page, use the name of the “Contact PD/PI, et. al.” The contact PD/PI must be from the applicant organization if PD/PIs are from more than one institution.

All individuals designated as PD/PI must be registered in the eRA Commons and must be assigned the PD/PI role in that system (other roles such as SO or IAR will not give the PD/PI the appropriate access to the application records). Each PD/PI must include their respective eRA Commons ID in the eRA Commons User Name field.

#### **Item 3b. Degree(s)**

Indicate up to three academic and professional degrees or other credentials, such as licenses (e.g., R.N.).

### Item 3c. Position Title

Provide the academic or professional title of the PD/PI. If more than one title, indicate the one most relevant to the proposed project (e.g., Professor of Biochemistry, Chief of Surgical Service, or Group Leader).

### Item 3d. Mailing Address

Provide complete information (including room number, building, and street address) necessary for postal delivery. All written communications with the PD/PI will use this address. For electronic mail, enter the appropriate e-mail address (not a website URL).

### Item 3e. Department, Service, Laboratory, or Equivalent

Indicate organizational affiliation, such as Department of Medicine, Materials Research Laboratory, or Social Sciences Institute.

### Item 3f. Major Subdivision

Indicate school, college, or other major subdivision, such as medical, dental, engineering, graduate, nursing, or public health. If there is no such subdivision, enter "None."

### Item 3g. Telephone and Fax Numbers

Provide a daytime telephone number and, if available, a fax number.

### Item 3h. eRA Commons User Name

The Commons User Name is the ID assigned to and used by the individual to access the [eRA Commons](#). All PD/PIs are required to be registered in the eRA Commons and **must** provide their Commons User Name.

## Item 4. Human Subjects Research

### No Human Subjects Involved

Check "No" if activities involving human subjects are not planned at any time during the proposed project period. The remaining parts of Item 4 are then not applicable.

### Human Subjects Involved

Check "Yes" if activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site or collaborating institution. Check "Yes" if the research is exempt from DHHS regulatory requirements for the protection of human subjects (see [Exemption Categories](#)).

If you plan to conduct research involving human subjects, but do not have definite plans at the time of application, you will need to include item 8 of the Research Plan. Certification of IRB review and approval must be provided and accepted by the awarding component before the research may occur.

NIH does not require certification of review and IRB approval of proposed research prior to NIH peer review of an application (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html> and Part II, [Human Subjects Research](#) supplemental instructions). However, any modification of the Research Plan section of the application required by the IRB or to address human subjects concerns raised during review, must be submitted for approval before award. See also the [Just-In-Time Policy](#) and [IRB Approval](#).

The DHHS regulations "Protection of Human Subjects" ([45 CFR Part 46](#), administered by OHRP) define a [human subject](#) as "a living individual about whom an investigator conducting research obtains: data through *intervention* or *interaction* with the individual or *identifiable private information*." See Part III.3 for the definitions of italicized terms used in the definition of human subject.

Regulatory requirements (Federal and state) to protect human subjects may apply to research using human specimens and/or data, such as use of:

- Bodily materials, such as cells, blood or urine, tissues, organs, hair or nail clippings, from living individuals who are individually identifiable to the investigator(s), even if these materials were collected by others;
- Residual diagnostic specimens from living individuals that are individually identifiable to the investigator(s), including specimens obtained for routine patient care that would have been discarded if not used for research;
- Private information, such as medical information, about living individuals that is individually identifiable to the investigator(s), even if the information was not specifically collected for the study in question. This includes research on genetic information that can be readily associated by the investigator(s) with identifiable living individuals.

Research that involves only *coded* private information/data or *coded* human biological specimens may not constitute human subjects research under the DHHS human subjects regulations (45 CFR Part 46) if:

- the specimens and/or private information were not collected specifically for the currently proposed research project through an interaction/intervention with living individuals AND
- the investigator(s) (including collaborators) on the proposed research cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researcher's access to subject identities is prohibited by written repository procedures and policies and/or through a written agreement signed by the investigator and the repository providing the specimens and/or data).

See definition of [coded](#) in Part III.3 under Human Subjects definitions, and the following guidance from the Office for Human Research Protections (OHRP) for additional information and examples: <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.

Individuals who provide *coded* information or specimens for proposed research and who also collaborate on the research involving such information or specimens are considered to be involved in the conduct of human subjects research as investigators (see definition of [human subjects](#)).

Additional information is available at:

- OHRP Decision Charts: <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>
- OHRP Guidance on Repositories: <http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>; <http://www.hhs.gov/ohrp/humansubjects/guidance/guid1223.pdf>
- OHRP Memo on Engagement: <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>
- NIH Office of Extramural Research Human Subjects website: <http://grants.nih.gov/grants/policy/hs/index.htm>.

#### **Item 4a. Exemptions from Department of Health and Human Services (DHHS) Human Subjects Regulations**

Check “Yes” if the activities proposed are exempt from the regulations at [45 CFR Part 46](#). Insert the exemption number(s) corresponding to one or more of the [six exemption categories](#) listed in Part III under Human Subjects Research Definitions and Terms.

OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (<http://www.hhs.gov/ohrp/humansubjects/guidance/irb71102.pdf>). Institutions often designate their

IRB to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated in item 4a often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

Proposed research may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research. Human subjects research should be designated as exempt if **all** of the proposed research meets the criteria for one or more of the six exemptions.

Check “No” if any of the planned activities involving human subjects are not exempt, and complete the remaining parts of Item 4.

#### **Item 4b. Human Subjects Assurance Number**

If the applicant organization has a current approved Federal Wide Assurance (FWA) on file with the OHRP (<http://www.hhs.gov/ohrp/>), enter the number in the space provided.

Enter “None” in Item 4b if the applicant organization does not have an approved FWA on file with OHRP. In this case, the signature on the Face Page is a declaration that the applicant organization will comply with [45 CFR Part 46](#) and proceed to obtain a FWA (see <http://www.hss.gov/ohrp/>).

**Do not enter the human subjects assurance number of any Project/Performance Site or collaborating institution in the space provided.**

#### **Item 4c. Clinical Trial**

Check “Yes” or “No” to indicate whether the project includes a clinical trial. Refer to the definition of “[clinical trial](#)” in Part III.3, under Human Subjects Research Definitions and Terms.

Note that Public Law 110-85, enacted 09/27/2007, mandates registration and results reporting of applicable clinical trials in ClinicalTrials.gov (see [Part II, 4.1.6](#) and [Part III, 2.1.6](#)).

#### **Item 4d. NIH-Defined Phase III Clinical Trial**

Check “Yes” or “No” to indicate whether the project is an NIH-Defined Phase III Clinical Trial. Refer to the definition of “[NIH-Defined Phase III Clinical Trial](#)” in Part III.3, under Human Subjects Research Definitions and Terms.

#### **Item 5. Vertebrate Animals**

Check “No” if activities involving vertebrate animals are not planned at any time during the proposed project period, and leave item 5a blank. Note that generation of custom antibodies constitutes an activity involving vertebrate animals.

Check “Yes” if activities involving vertebrate animals are anticipated or planned at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site or collaborating institution. If animal involvement is anticipated within the period of award but plans are indefinite and it is not possible to describe the use of animals, check “Yes” and in the Research Plan, item 12, provide an explanation and indicate when it is anticipated that animals will be used. Before activities with animals begin, the applicant must provide all of the information required by 5.5, Research Plan, item 12, Vertebrate Animals, with verification of current IACUC approval, to the awarding component for prior approval. IACUC approval must have occurred within the past three years to be considered current.

NIH does not require verification of review and approval of the proposed research by the Institutional Animal Care and Use Committee (IACUC) before peer review of the application. However, this information is required under [Just-In-Time Policy](#).

## Item 5a. Animal Welfare Assurance

If the applicant organization has a current approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), enter the Assurance number of the applicant organization in Item 5a. To determine whether the organization holds an Animal Welfare Assurance, contact the IACUC or see <http://grants.nih.gov/grants/olaw/olaw.htm#assur>.

Enter "None" in Item 5a if the applicant organization does not have an Animal Welfare Assurance on file with OLAW. **Do not enter the Animal Welfare Assurance number of any Project/Performance Site or collaborating institution.** The signature on the Face Page constitutes declaration that the applicant organization will comply with [PHS Policy on Humane Care and Use of Laboratory Animals](#) by submitting an Animal Welfare Assurance when requested by OLAW and providing verification of IACUC approval when requested by the PHS awarding component.

## Item 6. Dates of Proposed Period of Support

Request no more than 5 years of support, unless specifically authorized in the FOA. Note that some mechanisms specify fewer years.

**New application.** Consult the schedule at <http://grants.nih.gov/grants/dates.htm> for an appropriate beginning date. Refer to the FOA for beginning dates for PHS agencies other than NIH.

**Renewal application.** Choose a beginning date immediately following the termination date of the current period of support.

**Revision application.** **Submit a Revision application only for a period within the current period of the active grant.** At the time of submission, the Revision request must be within the time period of the original (parent) award period, and any extension must be done **before** submission. Make the ending date of the Revision's first budget period coincide with the ending date of the budget period that is to be supplemented, regardless of the Revision's beginning date. If requesting supplemental funds for the future years of a currently funded grant, make the future years' budget periods coincide with those of the currently funded grant.

## Budget Request

All amounts requested in Items 7 and 8 and on the budget pages must be in U.S. dollars.
-----------------------------------------------------------------------------------------

## Item 7. Costs Requested for Initial Budget Period

### Item 7a. Direct Costs

From Form Page 4, enter the "Subtotal Direct Costs for Initial Budget Period."

### Item 7b. Total Costs

Enter the sum of: 1) the "Total Direct Costs for Initial Budget Period" from Form Page 4 and 2) the Facilities and Administrative costs for the initial budget period, as calculated on the Checklist Form Page.

Note the "Total Direct Costs" used to calculate Item 7b includes any consortium F&A costs.

## Item 8. Costs Requested for Proposed Period of Support

### Item 8a. Direct Costs

From Form Page 5, enter the sum of "Subtotal Direct Costs" for all years.

### Item 8b. Total Costs

Enter the sum of: 1) "Total Direct Costs for Entire Proposed Project Period" from Form Page 5; and, 2) the total Facilities and Administrative costs for all years calculated on the Checklist Form Page.

Note the "Total Direct Costs" used to calculate Item 8b includes any consortium F&A costs.

### **Item 9. Applicant Organization**

Name the one organization that will be legally and financially responsible for the conduct of activities supported by the award.

### **Item 10. Type of Organization**

Check the appropriate box. See definitions of [Applicant Organization Types](#) definitions in Part III, 3.

### **Item 11. Entity Identification Number, DUNS Number, Congressional District**

**Entity Identification Number.** Enter the 12-digit Entity Identification Number (EIN) assigned to the applicant organization by the Department of Health and Human Services Payment Management System for payment and accounting purposes. This number is an expansion of the 9-digit EIN assigned by the IRS. If the institution has not yet been assigned a number, enter either (1) the organization's Internal Revenue Service employer identification number (nine digits) or (2) the words "Applied for" to indicate that the organization does not have an EIN but has applied to the local office of the IRS for one. **Do not enter the PD/PI's social security number**; it is not appropriate for this item.

**Data Universal Numbering System (DUNS) number.** Enter the DUNS number. Applicant organizations must provide a DUNS number when applying for Federal grants or cooperative agreements. The DUNS, a Universal Identifier 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 to enter. If the organization does not have a DUNS number, an authorized organizational official should complete the electronic [US D&B D-U-N-S Number Request Form](#) or contact Dun and Bradstreet by telephone directly at **1-866-705-5711 (toll-free)** to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual PD/PIs do not need to register for a DUNS number.

**Congressional District.** Enter the number of the Congressional District of the applicant organization. To locate the appropriate district see <http://congress.org/congressorg/dbq/officials/?lvl=L>.

### **Item 12. Administrative Official to be Notified if Award is Made**

Name the applicant organization administrative official to be notified if an award is made. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the administrative official.

### **Item 13. Official Signing for Applicant Organization**

Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the signing official.

### **Item 14. Applicant Organization Certification and Acceptance**

An original signature, in ink, is required. Only an institutional official with formal designated or delegated authority to sign on behalf of the organization may sign the form. The signature must be dated. *In signing the application Face Page, the Authorized Organizational Representative of the applicant organization certifies that the applicant organization will comply with all applicable policies, assurances and/or certifications referenced in the application.*

The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as

withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

## **Assurances and Certifications**

Each application to the PHS requires that the following policies, assurances and/or certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. These assurances are explained in [Part III: Policies, Assurances, Definitions, and Other Information](#). Applicants and grantees must comply with a number of additional public policy requirements. Refer to the institution's research grant administrative office or the [NIH Grants Policy Statement](#) (<http://grants.nih.gov/grants/policy/policy.htm>) for additional information.

The policies, assurances and certifications listed below may or may not be applicable to the project, program, or type of applicant organization:

[Human Subjects Research](#)

[Research on Transplantation of Human Fetal Tissue](#)

[Research Using Human Embryonic Stem Cells](#)

[Women and Minority Inclusion Policy](#)

[Inclusion of Children Policy](#)

[ClinicalTrials.gov Requirements](#)

[Vertebrate Animals](#)

[Debarment and Suspension](#)

[Drug-Free Workplace](#)

[Lobbying](#)

[Non-Delinquency on Federal Debt](#)

[Research Misconduct](#)

[Civil Rights](#)

[Handicapped Individuals](#)

[Sex Discrimination](#)

[Age Discrimination](#)

[Recombinant DNA, including Human Gene Transfer Research](#)

[Financial Conflict of Interest](#)

[Smoke-Free Workplace](#)

[Prohibited Research](#)

[Select Agent Research](#)



## 4.2 Description, Project/Performance Sites, Senior/key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells

[FORM PAGE 2](#) and 2-continued

Do NOT insert additional pages between Form Page 1 and Form Page 2.

### 4.2.1 Description: Project Summary and Relevance

The first and major component of the Description is a **Project Summary**. It is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and rationale and techniques for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person.

The second component of the Description is **Relevance**. Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

**DO NOT EXCEED THE SPACE PROVIDED.**

Do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the project description will be entered into an NIH database (Computer Retrieval of Information on Scientific Projects - CRISP) and will become public information.

### 4.2.2 Project/Performance Site(s)

Indicate where the work described in the Research Plan will be conducted. If there are more than two Project/Performance Sites, use the Project/Performance Site Format Page to list all the sites, including Department of Veterans Affairs (VA) facilities and foreign sites. Provide an explanation on the Resources Format Page of the application, and state whether a consortium/contractual arrangement is involved with one or more collaborating organizations for the conduct of a portion of the work described in the Research Plan. One of the sites indicated must be the applicant organization or be identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the Checklist Form Page of the application.

If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with [45 CFR Part 46](#) and other NIH human subject related policies described in the PHS 398 and [GPS](#).

For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold OLAW-approved Assurances. If the applicant organization does not have an animal program or facilities and the animal work will be conducted at an institution with an Assurance, the applicant must obtain an Assurance from OLAW prior to an award.

### 4.2.3 Senior/key Personnel

In addition to the PD/PI, Senior/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 Senior/key Personnel. **Consultants should also be included if they meet the same definition.**

Senior/key Personnel must devote measurable effort (described in person months) to the project, whether or not salaries are requested. "Effort of zero person months" or "as needed" are not acceptable levels of involvement for those designated as Senior/key Personnel.

**Start with the PD/PI(s).** List the PD/PI's last name first. When multiple PIs are proposed, list the contact PI first, then all additional PIs in alphabetical order. Then list all other Senior/key Personnel in alphabetical order, last name first. For each individual provide name, eRA Commons User Name (if known), organization name (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function on the proposed project. *Use additional consecutively numbered pages as necessary.*

### 4.2.4 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 (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may **not** be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition. This is also an appropriate designation for mentors on Career awards.

A biosketch, including Research Support information, will be required for Senior/key Personnel and OSCs, as this highlights their relevant accomplishments. Reviewers use these pages to address the "investigator" review criterion (see Research Project Evaluation Criteria in Section 6. The Peer Review Process).

However, if an award is to be made, Other Support information will not be required or accepted for OSCs since considerations of overlap do not apply to these individuals.

Should the level of involvement for an individual listed as an OSC increase to measurable effort, they must be redesignated as Senior/key Personnel. This change must be made before any compensation is charged to the project.

### 4.2.5 Human Embryonic Stem Cells

If the proposed project involves human embryonic stem cells, in this section list the registration number of the specific cell line(s) from the stem cell registry found at:

<http://stemcells.nih.gov/research/registry/>. Use continuation pages as needed. If a specific line cannot be referenced at the time of application submission, include a statement that one from the registry will be used.

## 4.3 Research Grant Table of Contents

### FORM PAGE 3

Provide the page number for each category listed on the Table of Contents. Place page numbers at the bottom of each page, and consecutively number pages throughout the application. **Do not include unnumbered pages, and do not use suffixes, such as 5a, 5b.**

## 4.4 Budget Instructions

### [FORM PAGE 4](#)

#### DETAILED BUDGET FOR INITIAL BUDGET PERIOD

Each item listed on Form Page 4 must be clearly justified on Form Page 5. List only the direct costs requested in this application. Do not include any items that are treated by the applicant organization as Facilities and Administrative (F&A) costs according to a Federal rate negotiation agreement, except for those F&A costs included in consortium/contractual costs.

**Note: If you are requesting a budget of \$500,000 direct costs or more for any year, you must obtain prior approval from Institute/Center staff. This limit is exclusive of any consortium F&A costs. If the subtotal Direct Costs on Form Page 5 equals or exceeds \$500,000 in any year, prior approval is required. (See [Policy on the Acceptance for Review of Unsolicited Applications That Request \\$500,000 or More in Direct Costs](#).)** The following items pertain individually to the completion of Form Page 4 (Detailed Budget for Initial Budget Period – Direct Costs Only).

#### Personnel

**Name.** Starting with the PD/PI(s), list the names of all applicant organization employees who are involved on the project during the initial budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

**Role on Project.** Identify the role of each individual listed on the project. Describe their specific functions under Justification on Form Page 5. Provide budget narrative for ALL personnel by position, role, and level of effort using person months (calendar, academic and/or summer). This includes any “to-be-appointed” positions.

**Months Devoted to Project.** Enter the number of months devoted to the project. Three columns are provided depending on the type of appointment being reflected: academic, calendar, and/or summer months. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, each appointment should be identified separately using the corresponding column.

If effort does not change throughout the year, use only the calendar months column. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for the requested period.

**Institutional Base Salary.** An applicant organization may choose to leave this column blank. However, PHS staff will require this information prior to award. See [Definitions in Part III.3](#).

**Salary Requested.** Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each individual listed.

Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. For guidance on current salary limitations see the [Salary Cap Summary](#) on the NIH grants Web site or contact the organization’s office of sponsored programs.

NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html>.

**Fringe Benefits.** Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.

**Totals.** Calculate the totals for each position and enter the subtotals in each column where indicated.

The applicant organization and its **consortium/contractor(s)** may omit salaries and fringe benefits for individuals from copies of the application that are available to non-Federal reviewers. In such cases, replace the numbers with asterisks. You must show the subtotals. Provide one copy, for use only by PHS staff, with the asterisks replaced by the salaries and fringe benefits.

### **Special Instructions for Joint University and Department of Veterans Affairs (VA) Appointments**

Individuals with joint university and VA appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the VA; and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work. Additional information may be requested by the awarding components.

### **Consultant Costs**

Whether or not costs are involved, provide the names and organizational affiliations of all [consultants](#), other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring or advisory committees. Describe the services to be performed on Form Page 5 under "Justification." Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

### **Equipment**

List each item of [equipment](#) with amount requested separately and justify each purchase on Form Page 5.

### **Supplies**

Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than \$1,000 do not have to be itemized. If animals are to be purchased, state the species and the number to be used.

### **Travel**

Itemize travel requests and justify on Form Page 5. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.

### **Patient Care Costs**

If inpatient and/or outpatient costs are requested for research with human subjects, provide the names of any hospitals and/or clinics and the amounts requested for each on Form Page 5.

State whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a DHHS-negotiated rate, the PHS awarding component can approve a provisional rate. Indicate, in detail, the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of Other Support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of General Clinical Research Centers/Clinical Translation Science Awards.

### **Alterations and Renovations**

Itemize by category and justify on Form Page 5 the costs of essential alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs. **Note, costs for any Alterations and Renovations (A&R) were previously unallowable from foreign institutions, international organizations and domestic applications with foreign subawards. However an HHS policy change now allows for minor A&R (<\$500,000) on these applications. When requesting minor A&R costs under this policy, provide detailed information on the planned A&R in the budget justification.**

### **Other Expenses**

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient travel, patient participation incentives, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission when budgeted separately from salary/fringe benefits. **Justify costs on Form Page 5.**

### **Consortium/Contractual Costs**

Each participating consortium/contractual organization must submit a separate detailed budget for both the initial budget period (Form Page 4) and the entire proposed project period (Form Page 5).

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including Facilities and Administrative (F&A) costs. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.

For each budget from a participating consortium/contractual organization, leave the "Consortium/Contractual Direct Costs" category blank and use the "Subtotal Direct Costs" category to total the consortium direct costs. When F&A costs are requested by a consortium organization, enter those costs in the "Consortium/Contractual F&A Costs" category for each supplementary budget. Provide the F&A cost base and rate information in the budget justification section. The "Total Direct Costs for Initial Budget Period" category can be used for the consortium/contractual Total Costs (Direct Costs plus F&A).

For the applicant organization budget, list the sum of all consortium/contractual costs (direct and F&A). Insert additional budget page(s) after Form Page 5, numbering them sequentially. (Do not use 5a, 5b, 5c, etc.)

### **Budget Totals for Applicant Organization**

For Face Page Item 7a, use the "Subtotal Direct Costs for Initial Budget Period" on Form Page 4.

For Face Page Item 7b, add together the "Total Direct Costs for Initial Budget Period" from Form Page 4 and the F&A costs calculated for the initial budget period on the Checklist Form Page.

For Face Page Item 8a, total the "Subtotal Direct Costs" for all years on Form Page 5 (see 4.5 below).

For Face Page Item 8b, add together the "Total Direct Costs for Entire Proposed Project Period" on Form Page 5 and the Total F&A costs for all years calculated on the Checklist Form Page.

### **Revision Application**

For a Revision application, show only those items for which additional funds are requested. If the initial budget period of the Revision application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

## 4.5 Budget for Entire Proposed Period of Support

### [FORM PAGE 5](#)

In the first column enter the budget category totals of the initial budget period costs from Form Page 4.

Enter the totals under each budget category for all additional years of support requested. Identify with an asterisk (\*), and justify any significant increases or decreases from the initial year budget. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support.

### **Justification for Foreign Application or Component**

If the applicant organization is a foreign institution, or if the project includes a foreign component, provide a justification on Form Page 5. Describe special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental characteristics that augment existing U.S. resources. Indicate whether similar research is being done in the United States. For a definition of [foreign component](#), see Definitions in Part III.3.

## 4.6 Biographical Sketch

### [BIOGRAPHICAL SKETCH FORMAT PAGE](#)

Follow the instructions on the Biographical Sketch Format Page. This section must contain the biographical sketches of all individuals listed as **Senior/key Personnel and Other Significant Contributors**, including consultants, following the order as listed on Form Page 2.

All individuals who have the PD/PI role **must** be registered in the eRA Commons, and **must** include the assigned Commons User Name. This information is required, and is equivalent to the "Credential, e.g., agency login" in the federal-wide SF 424 (R&R) Senior/Key Person Profile. For information on the eRA Commons, see <https://commons.era.nih.gov/commons/index.jsp>.

Use the sample format on the Biographical Sketch Format Page to prepare this section for **all** grant applications. The Biographical Sketch may not exceed 4 pages. This 4-page limit includes the table at the top of the first page. (See sample of a completed Biographical Sketch: <http://grants.nih.gov/grants/funding/phs398/phs398.html#biosample>.)

Complete the educational block at the top of the format page, and complete sections A, B, and C:

- A. Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.
- B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation. *When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: [http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm). Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are **not** accepted as appendix material.)*
- C. Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the

projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Do not confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are distinctly different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards and includes detailed financial information (see Part I, 4.6.1). NIH staff will request complete and up-to-date "Other Support" information *after* peer review. This information will be used to check that the proposed research is not already funded through other sources.

Information on Other Support beyond that required in the biographical sketch should NOT be submitted with the application.

## 4.6.1 Other Support Information

[OTHER SUPPORT FORMAT PAGE](#)

Do not submit unless 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 Senior/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 "Senior/key Personnel."
- If the support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, PD/PI, 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. Include institutional, federal, public and private sources of 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/Person Months:** For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Person months should be classified as academic,

calendar and/or summer. For a pending project, indicate the level of effort in person months 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.

### **Special Instructions for Individuals with Multiple Research Appointments (e.g., dual university/Department of Veterans Affairs appointments)**

When an individual holds multiple appointments involving support for research activities, information from each appointment must be included separately in the Other Support documentation. The support from each funding source should be clearly and separately delineated so that the separate appointments can be considered independently when determining any potential overlap.

List each appointment separately and include enough information on the type of appointment; (e.g., full time academic or 6/8 VA) so that an assessment of an individual's commitment can be made. Within each appointment, include appropriate sources of research support providing the standard detailed information cited above.

Note that when an individual has multiple appointments it is possible that the combined effort can result in excess of 12 calendar months (not from any one institution, but a combination of multiple appointments). In all cases, an individual's combined total professional effort must meet a test of reasonableness.

## **4.7 Resources**

### [RESOURCES FORMAT PAGE](#)

Follow the sample format and instructions on the Resources Format Page when completing information on resources available for the project. If there are multiple Project/Performance Sites the resources available at each site should be described. In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations, or employ useful collaborative arrangements. If research involving Select Agent(s) will occur at any Project/Performance Site(s), the biocontainment resources available at each site should be described.

## **4.8 Personal Data**

### [PERSONAL DATA FORM PAGE](#)

Follow instructions on the form. When multiple PD/PIs are proposed, this form is applicable to all PD/PIs. Place the form(s) at the end of the original application. **Do not copy.**

## **4.9 Senior/key Personnel Report**

### [SENIOR/KEY PERSONNEL REPORT FORMAT PAGE](#) - Renewal Applications Only

Use **only** when requested by the awarding component.

List all [Senior/key Personnel](#), salaried and unsalaried, at the applicant organization or elsewhere, who participated in the project during the current budget period. Include all degrees, role on project, date of birth, number of person months devoted to the project (indicate academic, calendar, and/or summer) and the last four digits of the Social Security number. When requesting this portion of the Social



Security numbers from personnel, explain that provision of the Social Security number is voluntary, and the information will be used only for program management purposes.

Individuals designated as Other Significant Contributors, e.g. those that may contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project, should **not** be included in this report unless their involvement has changed so that they now meet the definition of "Senior/key Personnel."

## **5. Preparing the Research Plan, the Checklist, and the Appendix**

### **5.1 (Reserved)**

### **5.2 (Reserved)**

### **5.3 (Reserved)**

## **5.4 Research Plan Format and Notice of Proprietary Information**

### **5.4.1 Research Plan Format**

No Specific Form Page - Use [CONTINUATION PAGE](#)

The Research Plan consists of items 1-17 in Section 5.5 below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies. For grant writing tips, see [http://grants.nih.gov/grants/grant\\_tips.htm](http://grants.nih.gov/grants/grant_tips.htm). Carefully follow all instructions.

#### **Page Limitations**

**Do not exceed 25 pages for Items 2-5.** All tables, graphs, figures, diagrams, and charts must be included within the 25-page limit. Be succinct and remember that there is no requirement to use all 25-pages allotted to Items 2-5. Recommended page numbers for items 2-4 are included in the instructions below. If PAs or RFAs contain specific page limitations, those instructions supersede these PHS 398 instructions.

#### **Use of URLs**

Unless otherwise specified in a solicitation, do not use Internet website addresses (URLs) to provide information because reviewers are not obligated to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an internet site (except to review publications cited in the Biographical Sketch or Progress Report Publication List) because this may compromise their anonymity.

#### **Other Materials**

Do not include photographs or other materials that are not printed directly on the application page in the body of the application. Pictures or other materials glued or taped into the application pages are incompatible with the duplication/scanning process.

PDF images of material such as electron micrographs or gels may be included in the Appendix; however, a photocopy of each must also be included within the page limitations of the Research Plan (see [Section 5.7](#)).

## 5.4.2 Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is confidential or privileged, identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (\*) at the beginning of the paragraph. Indicate at the beginning of the Research Plan which pages contain asterisks and a note stating: "*The following sections marked with an asterisk contain proprietary/privileged information that [name of applicant] requests not be released to persons outside the Government, except for purposes of review and evaluation.*"

When information in the application constitutes trade secrets or information that is commercial or financial, or information that is confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

## 5.5 Content of Research Plan

The Research Plan consists of the following items, as applicable. Begin each section of the Research Plan with a section header (e.g., Introduction, Specific Aims, etc.). Organize Items 2-5 of the Research Plan to answer these questions: *What do you intend to do? Why is the work important? What has already been done? How are you going to do the work?* Remember that Items 2-5 may not exceed 25 pages, including all tables and figures.

1. Introduction to Application (Resubmission or Revision Applications only)
2. Specific Aims
3. Background and Significance
4. Preliminary Studies/Progress Report
5. Research Design and Methods
6. Inclusion Enrollment Report (Renewal or Revision Applications only)
7. Bibliography and References Cited/Progress Report Publication List
8. Protection of Human Subjects
9. Inclusion of Women and Minorities
10. Targeted/Planned Enrollment Table
11. Inclusion of Children
12. Vertebrate Animals
13. Select Agent Research
14. Multiple PD/PI Leadership Plan
15. Consortium/Contractual Arrangements
16. Letters of Support (e.g., Consultants)
17. Resource Sharing Plan(s)

## 1. Introduction (Resubmission or Revision Applications only)

All Resubmission and Revision applications must include an Introduction. The Introduction may not exceed three pages for Resubmission applications, or one page for Revision applications. See specific instructions in [2.7 Resubmission Applications](#) and [2.8 Revision Applications](#) on the content of the Introduction. Place the Introduction at the very beginning of the Research Plan.

## 2. Specific Aims

List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. **One page is recommended.**

## 3. Background and Significance

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. **Two to three pages are recommended.**

## 4. Preliminary Studies/Progress Report

***(a) Preliminary Studies.*** For new applications, use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.

Peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

***(b) Progress Report for Renewal and Revision Applications.*** A Progress Report must be provided for Renewal and Revision applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Discuss any changes in the specific aims as a result of budget reductions.

A list of publications, manuscripts accepted for publication, patents, and other printed materials will be included in Item 7.b; do not include that information here.

**Six to eight pages are recommended.**

## 5. Research Design and Methods

Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 17, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Although no specific number of pages is recommended for the Research Design and Methods section, be as succinct as possible. There is no requirement that all 25 total pages allotted for items 2-5 be used.

## 6. Inclusion Enrollment Report (Renewal or Revision Applications only)

If the Renewal or Revision application involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender using the Inclusion Enrollment Report for each protocol.

## 7. Bibliography and References Cited/Progress Report Publication List

When citing articles in (a) or (b) below that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: [http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm). Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see [Section 5.7](#)).

***(a) Bibliography and References Cited*** - Provide a bibliography of any references cited in the description of the Project Summary and Relevance (Form Page 2). Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.

*The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.*

***(b) Progress Report Publication List*** - For Renewal applications list the title and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

## 8. Protection of Human Subjects

Refer to Part II of the PHS 398: [Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan](#) if the proposed research will involve human subjects.

## 9. Inclusion of Women and Minorities

To determine if Inclusion of Women and Minorities applies to the application, see Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan, Sections [4.2](#) and [5.6](#).

## 10. Targeted/Planned Enrollment Table

If this application involves the Inclusion of Women and Minorities, complete the Targeted/Planned Enrollment Table for each protocol; see Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan, [Section 4.3](#).

## 11. Inclusion of Children

To determine if Inclusion of Children applied to this application, see Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan, Sections [4.4](#) and [5.7](#).

## 12. Vertebrate Animals

If vertebrate animals are involved in the project, address each of the five points below.

If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating sites), identify those sites and describe the activities at those locations.

Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following five points will result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application's priority score may be negatively affected.

The five points are as follows:

1. Provide a detailed description of the proposed use of the animals for the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reason(s) for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used.

### **13. Select Agent Research**

Select Agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents; see <http://www.cdc.gov/od/sap/docs/salist.pdf>.

If the activities proposed in the application involve only the use of a strain(s) of Select Agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.4(f)(5), the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at <http://www.cdc.gov/od/sap/sap/exclusion.htm>.

If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of the request or the intent to apply for an exclusion and provide a brief justification for the exclusion.

If any of the activities proposed in the application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the Select Agent(s) to be used in the proposed research.
2. Provide the registration status of all entities\* where Select Agent(s) will be used.

- If the Project/Performance Site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed.

\*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”

3. Provide a description of all facilities where the Select Agent(s) will be used.

- Describe the procedures that will be used to monitor possession, use and transfer of Select Agent(s).
- Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

If you are responding to a specific Funding Opportunity Announcement (e.g., PA or RFA), address any requirements specified by the solicitation.

Reviewers will assess the information provided in this section, and any questions associated with Select Agent research will need to be addressed prior to award.

#### **14. Multiple Project Director/Principal Investigator (PD/PI) Leadership Plan**

For applications designating multiple PD/PIs, a leadership plan must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs, including responsibilities for human or live vertebrate animal subject studies as appropriate.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award.

#### **15. Consortium/Contractual Arrangements**

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). For applications including multiple PD/PIs, this information may be included as part of the Leadership Plan above. If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

The signature of the authorized organizational official on the Face Page signifies that the applicant and all proposed consortium participants understand and agree to the following statement: *The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency’s consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.*

#### **16. Letters of Support (e.g., Consultants)**

Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For consultants, letters should include rate/charge for consulting services. Do **not** place these letters in the Appendix. Consultant biographical sketches should be in the Biographical Sketch section.

## 17. Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

(a) *Data Sharing Plan*: Investigators seeking \$500,000 or more in direct costs in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss data-sharing plans with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See [Data-Sharing Policy](#) or <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state appropriate reasons why such sharing is restricted or not possible. See [Sharing Model Organisms Policy](#), and [NIH Guide NOT-OD-04-042](#).

(c) *Genome-Wide Association Studies (GWAS)*: Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, [NIH Guide NOT-OD-07-088](#), and <http://grants.nih.gov/grants/gwas/>.

## 5.6 Checklist

[CHECKLIST FORM PAGE](#)

### Type of Application

Check all that apply.

### Inventions and Patents (Renewal Applications Only)

If no inventions were conceived or reduced to practice during the course of work under this project, check "No." The remaining parts of the item are then not applicable.

If any inventions were conceived or reduced to practice during the previous period of support, check "Yes." Also indicate whether this information has been reported previously to the PHS or to the applicant organization official responsible for patent matters.

Note: NIH recipient organizations must promptly report inventions to the Extramural Inventions and Technology Resources Branch of the Office of Policy for Extramural Research Administration, OER, NIH, Bethesda, MD 20892-2750, (301) 435-1986. Invention reporting compliance according to regulations at 37 CFR 401.14 is described at <http://www.iedison.gov>. The grantee is encouraged to submit reports electronically using Interagency Edison (<http://www.iedison.gov>). See also "[Inventions and Patents](#)" in Part III, 1.6.

### 1. Program Income

If no [program income](#) is anticipated during the period(s) for which grant support is requested, so state.

If program income is anticipated, use the format provided. If the application is funded, the Notice of Award will provide specific instructions regarding the use of such income.

## 2. Assurances/Certifications

Each application to the PHS requires that the policies, assurances, and certifications provided in Part III and listed in Part 1, 4.1 under Item 14, be verified by the signature of the official signing for the applicant organization on the Face Page of the application.

## 3. Facilities and Administrative (F&A) Costs

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the Division of Financial Advisory Services (DFAS), NIH. If the applicant organization does not have a current negotiated rate, it should develop a provisional rate for application purposes, and immediately upon notification that an award will be made, it should submit the provisional F&A cost rate proposal to the appropriation negotiation office. This proposal is to be based on the organization's most recently completed fiscal year in accordance with the principles set forth in the pertinent DHHS guidance for establishing indirect cost rates, and submitted to the appropriate DHHS Regional Office or the DFAS, NIH. If the applicant organization has a current negotiated rate with another Federal agency, the negotiated rate must be adjusted to treat any independent research and development (IR&D) costs in accordance with DHHS policy. F&A costs will NOT be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for [Career Development Awards](#), [Institutional Training, including Ruth L. Kirschstein National Research Service Awards](#), foreign grants, and specialized grant applications.

## 4. Disclosure Permission Statement

In the case this application does not result in an award, check "yes" to provide permission for the Government to disclose the title of the proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment). Check "no" if you do not provide this permission. Your response will not affect any peer review or funding decisions.

## 5.7 Appendix

Do not use the appendix to circumvent the page limitations of the Research Plan. Graphs, diagrams, tables, and charts should be included in the body of the Research Plan unless a PDF file is necessary to show detail. Not all grant mechanisms allow publications to be included in the appendix. When publications are allowed, a limit of 3 publications, which are not publicly available, will be considered in the initial peer review (see below for further details and check the FOA for any specific instructions). A summary listing all of the items included in the appendix is encouraged, but not required. When including a summary, it should be the first file on the CD. Applications that do not follow the appendix requirements may be delayed in the review process.

Five identical CDs containing all appendix material must be submitted in the same package with the application. When preparing CDs:

- Use PDF format. Where possible, applicants should avoid creating PDF files from scanned documents. NIH recommends producing the documents electronically using text or work-processing software and then converting to PDF. Scanned documents are generally of poor quality and difficult to read.
- Label each disk with the PD/PI name and application title.
- If burning CD-ROM disks on a Mac, select the ISO 9660 format.



- Do not use compression techniques for the electronic files.
- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

The following materials may be included in the appendix to New, Revision, Renewal and Resubmission applications:

- Up to 3 publications of the following types. In each case include the entire document:
  - Manuscripts and/or abstracts accepted for publication but not yet published.
  - Published manuscripts and/or abstracts where a free, online, publicly available journal link is not available.
  - Patents directly relevant to the project.

Do not include unpublished theses or abstracts/manuscripts submitted, but not yet accepted, for publication.

- Surveys, questionnaires, and other data collection instruments, clinical protocols, and informed consent documents.
- Color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 25-page limit of Items 2-5 of the Research Plan. No images may be included in the appendix that are not also represented within the Research Plan.
- For materials that cannot be submitted on CD (e.g., medical devices, prototypes), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Publications that are publicly accessible must not be included in the appendix. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References Cited/Progress Report Publication List section of the Research Plan, and/or in the Biographical Sketch.

## 6. The Peer Review Process

### Overview

NIH policy is intended to ensure that applications for funding submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Proposals" ([42 CFR Part 52h](#)).

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils are composed of both scientific and lay members chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council may be recommended for funding. Only the NIH Institute or Center may make actual funding decisions.

A detailed description of what happens to a research project grant application after it is received for peer review can be found at the following location:

[http://grants.nih.gov/grants/peer\\_review\\_process.htm](http://grants.nih.gov/grants/peer_review_process.htm). Additional information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate agency.

Information on CDC review procedures is located at <http://www.cdc.gov/od/science/PHResearch/peerreview.htm>.

Note: Applications received for potential FY2009 funding will be evaluated using the review criteria adopted October 12, 2004 (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html>) and modified May 11, 2006 (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-069.html>). The enhanced review criteria and scoring procedures below have been issued for the evaluation of research applications received for potential FY2010 funding and thereafter.

## Streamlining

The initial scientific peer review of most applications will also include a process in which only those applications deemed by the reviewers to have the highest scientific merit, generally the better half of the applications under review, will be discussed at the SRG meeting, assigned an impact score, and receive a second level review. Applications in the lower half are reviewed by SRG members but they are not discussed or scored at the SRG meeting. This process allows the reviewers to focus their discussion on the most meritorious applications.

Before the review meeting, each reviewer and discussant assigned to an application will give a separate score for each of the five core review criteria and a preliminary impact score for that application (see below). The preliminary impact scores will be used to determine which applications will be discussed.

## Scoring

SRG members are instructed to evaluate research applications by addressing the five core review criteria (see below) and additional review criteria as applicable for the application. However, Requests for Applications (RFAs) and other types of funding opportunities (e.g., construction grants and fellowship applications) may list different and/or additional review criteria and considerations.

For each application that is discussed, a final impact score will be given by each eligible committee member (without conflicts of interest) following the panel discussion. Each member's impact score will reflect his/her evaluation of the overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer's scores given to each criterion. The final impact score for each discussed application will be determined by calculating the arithmetic average of all the eligible members' impact scores, and multiplying the average by 10.

As part of the initial merit review, and regardless of whether an application is discussed or not discussed (streamlined), all applicants will receive a written critique, called a Summary Statement, unless stated otherwise in the FOA. The Summary Statement represents a combination of the reviewers' written comments and scores for individual criteria. The Summary Statement for discussed applications includes the Scientific Review Officer's summary of the members' discussion during the study section meeting; the final impact score; the recommendations of the study section, including budget recommendations; and administrative notes of special considerations. For applications that are not discussed by the full committee, the scores of the assigned reviewers and discussants for the five core criteria will be reported individually on the Summary Statement. Final impact scores are not given for applications that are not discussed.

## Research Project Evaluation Criteria

**Overall Impact.** Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

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

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

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

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

**Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

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

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

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

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

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

**Vertebrate Animals.** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the

animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

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

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

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

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

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

**Resource Sharing Plans.** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan ([http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)); 2) Sharing Model Organisms (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>); and 3) Genome Wide Association Studies (GWAS) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>).

## Dual-Level Peer Review

The second level of review will usually be performed by the Advisory Council or Board of the potential awarding component (Institute, Center, or other unit). Council or Board recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study to an Institute/Center's mission, programs and priorities.

## 7. Instructions for Preparing an Individual Research Career Development Award (CDA) Application – “K” Series

### 7.1 Introduction

This section includes additional instructions to be used when applying for an individual Research Career Development Award (CDA): a substitute Table of Contents (CDA Substitute Form Page 3), a summary of current CDA mechanisms, and guidelines for letters of reference. The instructions in this section of the PHS 398 application should be used along with the instructions in the preceding sections.

These instructions do not cover applications for K12 and other institutional career development programs. Institutions planning such applications should contact the potential awarding component concerning eligibility, award criteria, and application procedures. Some K-series funded through Requests for Applications (RFAs) may have special instructions.

#### Summary of Research Career Development Award Mechanisms

PROGRAM	DESCRIPTION	MENTOR	REFERENCE LETTERS
K01	Mentored Research Scientist Development Award	Yes	Yes
K02	Independent Scientist Award	No	No
K05	Senior Scientist Award	No	No
K07	Academic Career Award	*	*
K08	Mentored Clinical Scientist Development Award	Yes	Yes
K18	Career Enhancement Award (see specific IC)	Yes	Yes
K22	Career Transition Award (see specific IC)	*	Yes
K23	K23 Mentored Patient-Oriented Research Career Development Award	Yes	Yes
K24	Mid-Career Investigator Award in Patient Oriented Research	No	No
K25	Mentored Quantitative Research Career Development Award	Yes	Yes
K26	Midcareer Investigator Award in Mouse Pathobiology Research	No	No
K99/R00	NIH Pathway to Independence (PI) Award (K99/R00)	Yes	Yes

\* Varies with career status and source of award. Check the program announcement (PA).

### 7.2 Individual Career Development Award Mechanism

Before applying for a CDA, applicants should carefully review the guidelines in the NIH or other PHS agency Funding Opportunity Announcement (FOA) including Program Announcement (PA) or Request for Application (RFA) for the specific career award(s) of interest, noting especially the eligibility requirements, award provisions, requirements for a mentor, and review criteria. NIH and other agency program announcements and requests for applications for career awards are issued

periodically in the [NIH Guide for Grants and Contracts](#). The PAs and other guidelines are available on the NIH website <http://grants.nih.gov/training/careerdevelopmentawards.htm>.

The eligibility criteria, support levels, and other important aspects of specific career awards, including availability, may vary among NIH Institutes or Centers and other PHS agencies. For this reason, it is strongly recommended that applicants consult with the NIH Scientific/Research contact of the appropriate awarding component prior to the preparation of an application. For NIH career awards, the program contacts are listed in the individual FOA for each CDA (see K Kiosk: <http://grants.nih.gov/training/careerdevelopmentawards.htm>). For non-NIH career awards, applicants should read the instructions of the appropriate FOA carefully or contact an official. (See [Agency Contact table](#).)

Note: A few individual K-series programs supported by the NIH include a delayed award activation and/or two award phases (e.g., K22, K99/R00). NIH intramural researchers may be eligible to apply for these mechanisms. The FOA will include any additional and/or specific instructions that must be followed when applying for such support.

## 7.3 Letters of Reference

Three letters are required for all new and resubmission mentored CDA applications (see table of [Career Development Award Mechanisms](#), Section 7.1). **Applications with fewer than three reference letters may be delayed or may be returned without review.** These letters should be from individuals not directly involved in the application, but who are familiar with your qualifications, training, and interests. A letter of reference may be submitted by an individual not directly involved in the proposed research project; e.g., advisory committee members (if applicable). However, **the mentor(s) of this application must not submit a letter of reference because a mentor's statement is required as part of the application (Section 7.6.2).**

The letters are critically important and should address the candidate's competence and potential to develop into an independent biomedical or behavioral investigator. Only those individuals who can make the most meaningful comments about the candidate's professional training and qualifications for a research career should be used as referees. Where possible, some referees who are not from the candidate's current department or organization, but are knowledgeable about their qualifications, should be selected.

Request reference letters only from individuals who are able to return them to you in time for submission with the application.

Complete the upper section of the CDA Reference Guidelines Format Page including the application submission deadline. Then send copies of the CDA Reference Guidelines Format Page to those who have agreed to serve as referees. Referees should be provided with postage-paid return envelopes addressed to the candidate with the following words in the front bottom left corner "DO NOT OPEN PHS USE ONLY." **Attach unopened envelopes to the Face Page of the original application and submit the entire package by the submission deadline. Resubmission applications must include a complete set of three reference letters.**

## 7.4 Basic Administrative Data

### 7.4.1 Form Page 1

Complete as directed in the previous [Section 4. Completing the PHS 398 Forms and Format Pages](#), except items 2, 3, and 6, which are to be completed in accordance with the following instructions:

## **Item 2. Response to Specific Program Announcement (PA) or Request for Applications (RFA)**

Check "Yes." Provide appropriate K Award PA or RFA number ([see previous section](#)) and title for the specific type of CDA requested.

## **Item 3. Program Director/Principal Investigator (PD/PI)**

Provide the name of the candidate who is the PD/PI. Indicate the doctoral degree(s) in 3b. If the candidate is not located at the applicant organization at the time the application is submitted, the mailing and e-mail addresses (Item 3d) and telephone (Item 3g) should indicate where the applicant can be reached prior to the requested award date; items 3c, 3 e, and 3f should reflect the candidate's projected position at the applicant organization. Multiple PD/PI applications are not accepted for CDAs.

## **Item 6. Dates of Proposed Period of Support**

The period of support must be within specified limits for the type of CDA requested. If the application involves a change of applicant organization for an active CDA awardee, indicate the time remaining in the original award.

## **7.4.2 Description, Project/Performance Sites, Senior/key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells**

### [FORM PAGE 2](#)

#### **Description: Project Summary and Relevance**

The first major component of the Description is a **Project Summary**. Provide an abstract of the entire application. Include the candidate's immediate and long-term career goals, research project and career development plan, and the research environment.

The second component of the Description is **Relevance**. Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

#### **Project/Performance Site(s)**

Indicate where the work described in the Research and Career Development Plans will be conducted. If there is more than one Project/Performance Site, list all the sites, including Department of Veterans Affairs (VA) facilities and foreign sites.

If research involving human subjects is planned, whether at the grantee institution or at a Project/Performance Site, the grantee is responsible for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The grantee must assure that Project/Performance Sites comply with requirements set forth in the DHHS regulations ([45 CFR Part 46](#)) to protect human subjects and NIH policies that apply to clinical research described in the PHS 398, Part II. For research involving vertebrate animals, the applicant organization must ensure that all Project/Performance Sites have an assurance approved by the NIH Office of Laboratory Animal Welfare (OLAW).

#### **Senior/key Personnel and Other Significant Contributors**

**Note:** For the purposes of the CDA, the candidate is generally listed as Senior/key Personnel, and all other individuals are listed as Other Significant Contributors.

Name the candidate and, if applicable, the mentor(s), co-mentor(s), consultants, advisory committee members (if applicable), and contributors as Senior/key Personnel or as Other Significant Contributors as described in [Section 4.2.3, and Section 4.2.4, respectively](#). Individuals identified as Senior/key Personnel must devote measurable effort (described in person months) to the proposed project

whether or not salaries are requested. Individuals who have committed to contribute to the scientific development and execution of the project, but are not committing any specified measurable effort to the proposed project should be identified as Other Significant Contributors. Please note that for Mentored Career Development Awards, Other Support Pages must be submitted for mentor(s) and co-mentor(s) even though they are designated as other significant contributors (see [Section 7.4.7](#) below).

For non-mentored CDAs, provide the name of the candidate's department head or other senior staff member who is responsible for ensuring that the candidate's time is protected for the expressed goals of the award.

## Human Embryonic Stem Cells

If the Research Plan involves the use of human embryonic stem cells, read and follow the instructions in [Section 4.2.5](#).

### 7.4.3 Table of Contents

#### [CDA SUBSTITUTE FORM PAGE 3](#)

Use the **substitute** Table of Contents for CDAs.

#### **Citizenship**

All applicants must provide information regarding citizenship at the bottom of the substitute Table of Contents. For Career awards other than the K99 program, the Candidate must be a citizen or non-citizen national of the United States or its possessions and territories, or must have been lawfully admitted to the United States for permanent residence by the time of the award. The option of selecting "Non-citizen with temporary visa" is applicable to K99 candidates only.

### 7.4.4 Detailed Budget for Initial Budget Period

#### [FORM PAGE 4](#)

**Do not include Form Page 4 at the time of application unless it is specifically requested in the FOA to which you are responding.** Should Form Page 4 be requested prior to award, specific instructions will be provided.

If you are submitting an application to an agency other than NIH, be sure to read the instructions in the funding announcement to determine whether the application should be submitted in the modular format; or contact an appropriate official. (See [PHS Agency Contact Table](#).)

### 7.4.5 Budget for Entire Proposed Period of Support

#### [FORM PAGE 5](#)

Do not fill in the budget table on Form Page 5. Provide only the total direct costs requested for each year and total direct costs for the entire proposed period of support. **Consult the relevant PA or RFA for guidelines on allowable costs and budget limitations.** Begin the budget justification in the space provided; use continuation pages as needed.

#### **Budget Justification**

List the name, role on project, and number of person months to be devoted to the project (indicate academic, calendar, and/or summer) for all project personnel (salaried or unsalaried) and provide a narrative justification for each person based on his/her role on the project and proposed level of effort.

All individual "K" awards require a minimum percent of full-time professional effort to be devoted to the career development program which is specified in each FOA. For information about "Determining Full-



Time Professional Effort for Career Awards” see NIH Notice, [NOT-OD-04-056](#) released August 3, 2004.

Identify all consultants by name and organizational affiliation, and describe the services to be performed.

Provide a narrative justification for any major budget items, other than personnel, that are requested for the conduct of the project that would be considered unusual for the scope of research. **No specific costs for items or categories should be shown.**

## 7.4.6 Biographical Sketch

### [BIOGRAPHICAL SKETCH FORMAT PAGE](#)

A biographical sketch (**limited to four pages for each person**) is required for the candidate, mentor(s), co-mentor(s), and Senior/key Personnel and Other Significant Contributors included on Form Page 2-continued. Biographical sketches for individuals other than the candidate should follow the Biographical Sketch Format Page, and appear in the order listed on Form Page 2-continued.

**The biographical sketch for the candidate should follow the instructions below:**

#### **Education**

Provide the month and year for each degree conferred. For non-degree education, indicate the time period covered. List professional certifications received within the last 10 years.

#### **Research and/or Professional Experience**

Use the headings given below instead of the instructions on the Biographical Sketch Format Page. Identify each heading.

##### **Employment**

Start with the first position held following the baccalaureate and give a consecutive record to date. Indicate the department and organization, department head or supervisor, rank, tenured or non-tenured, status (full- or part-time), and inclusive dates. Where applicable, include information on military service, internships, residencies, research assistantships, fellowships, etc.

##### **Honors**

List academic and professional honors chronologically, including research grants and fellowships awarded to the candidate.

##### **Professional Societies and Public Advisory Committees**

Identify professional societies and related organizations in which membership has been held within the last 10 years, giving dates. Include present membership on any Federal Government public advisory committee.

##### **Publications**

List all publications (chronologically), divided into the following groups:

- Original research and theoretical treatises;
- Non-experimental articles, e.g., review of literature in field, book chapters, etc.;
- Books, pamphlets, etc.
- The list should include the title and complete references. If the list of publications cannot be accommodated within the four-page limit, select the most pertinent publications. If a copy of a publication is being submitted with the application, indicate with an asterisk and footnote "copies sent." For Renewal applications (when

applicable), also identify with a double asterisk and appropriately footnote all papers published during the previous period of support.

When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: [http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm). Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material.)

## 7.4.7 Other Support Format Page

### OTHER SUPPORT FORMAT PAGE

**For mentored CDAs** (see [Summary of Award Mechanisms table](#)): Submit modified Other Support Page(s) (omitting details of scientific overlap and level of effort) for the mentor(s) and co-mentor(s), but not for the candidate. Provide information on the following selected items for the mentor's and co-mentor's current and pending research support relevant to the candidate's Research Plan.

#### **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.

Do not include information on overlap and level of effort.
------------------------------------------------------------

**For non-mentored CDAs (e.g. K24):** Candidates for non-mentored CDAs should not submit Other Support Pages at the time of application unless specified to do so in the applicable FOA.

Updated information on all active support for the candidate, mentor(s), co-mentor(s), and Senior/key Personnel may be requested by the awarding component prior to award.

## 7.4.8 Resources

### RESOURCES FORMAT PAGE

For each Project/Performance Site listed on page 2, provide a detailed description of the career development program related activities and institutional resources available to you, following instructions on the Resources Format Page. The information provided is of major importance in establishing the feasibility of the goals of the career development plan.

## 7.5 Career Development Plan

Use [CONTINUATION FORMAT PAGES](#) to complete the sections below.

**Note: The total number of pages for Section 7.5.1 (The Candidate) and Section 7.5.4 (Research Plan) combined may not exceed 25 pages.** In many cases, CDA applications will be shorter than the limit.

### 7.5.1 The Candidate

Note: The total number of pages for Section 7.5.1 (The Candidate) and items 2-5 of Section 7.5.4 (Research Plan: this Section) combined may not exceed 25 pages. In many cases, CDA applications will be shorter than the limit.

#### Candidate's Background

Use this section to provide any additional information not described in the Biographical Sketch Format Page such as research and/or clinical training experience.

#### Career Goals and Objectives: Scientific Biography

Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. It is important to justify the award and how it will enable you to develop or expand your research career. You may include a timeline, including plans to apply for subsequent grant support.

#### Career Development/Training Activities During Award Period

Stress the new enhanced research skills and knowledge you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career. For mentored awards, describe structured activities, such as course work or technique workshops, which are part of the developmental plan. If course work is included, provide course numbers and descriptive titles. Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year, and explain how the activity is related to the proposed research and the career development plan.

Note that recipients of mentored “K” awards may receive concurrent support from an NIH research grant award or cooperative agreement only under certain conditions (see NIH Notice [NOT-OD-04-007](#) released November 14, 2003).

#### Training in the Responsible Conduct of Research

**All CDA applications must describe a plan to acquire training (or provide training in the case of independent awards, e.g., K05, K24) in the responsible conduct of research.** There are no specific curriculum or formal requirements for this instruction; however, conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, data management, and data-sharing are areas that are strongly suggested for consideration. Applicants may wish to consult the NIH web site (<http://www.nih.gov/sigs/bioethics/researchethics.html>) for additional guidance.

### 7.5.2 Statements by Mentor, Co-mentor(s), Consultant(s), and Contributor(s)

This section is to be completed by the mentor, co-mentor(s), consultant(s), and contributor(s), as appropriate.

For mentored awards (see [Summary of Career Development Award Mechanisms table](#)), the mentor must explain how they will contribute to the development of the candidate's research career. This explanation should include all of the following:

1. The plan for the candidate's training and research career development. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project.
2. The source of anticipated support for the candidate's research project for each year of the award period.
3. The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period.
4. The candidate's anticipated teaching load for the period of the award (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.
5. A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. The mentor should describe previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes.

All mentored career development applications should identify all co-mentors, consultants and collaborators involved with the proposed research and career development program. Briefly describe their roles and anticipated contributions. A co-mentor must specifically address the nature of his/her role in the career development plan and how the responsibility for the candidate's development is shared with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Also describe the nature of any resources that will be committed to this CDA. Letters from the mentor(s), co-mentor(s), consultant(s), advisory committee members (if applicable), and contributor(s) documenting their role and willingness to participate in the project must be included in this section of the application. Do not place these letters in the Appendix.

**Non-mentored career development award applications** should list any contributors or consultants. Briefly describe research materials, data, guidance, or advice they will provide. Letters from consultant(s) and contributor(s), documenting their willingness to participate in the project and describing their roles, must be included in this section of the application.

**Plan to Provide Mentoring, if required by FOA (e.g., K05, K24):** The plan should provide information about the candidate's commitment to serve as a mentor to other investigators, and describe previous mentoring activities. The plan should describe the setting and provide information about the available pool of mentees with appropriate backgrounds and interests in the same field of science. It should also include information on the candidate's past and proposed mentees sufficient to evaluate the quality of prior mentoring experiences, including the professional levels of mentees, and the frequency and kinds of mentoring interactions between the candidate and the mentees. Describe the productivity of the mentoring relationship for the scientific development of the new scientists as judged by their publications and current research activities. Senior level (K05) candidates should describe any financial and material support from their own funded research and research resources that will be available to their mentees. The candidate's proposed percent effort commitment to the mentoring plan should also be stated.

## 7.5.3 Environment and Institutional Commitment to the Candidate

### Description of Institutional Environment

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the [resources](#) description (Resources Format Page), indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

### Institutional Commitment to the Candidate's Research Career Development

#### Introduction

The institution should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the CDA. The document should include the institution's agreement to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured research career development experience. It is essential to document the institution's commitment to the retention, development and advancement of the candidate during the period of the award.

Because of the diverse types of K awards, applicants should contact the appropriate awarding component Scientific/Research contact listed in the specific PA or RFA to determine the level of commitment required for this application.

#### Agreement

The applicant organization must:

- a. Agree to release the candidate from other duties and activities to devote the required percentage of time for development of a research career. For most K awards, commitment of at least 75 percent of time is required. Describe actions that will be taken to ensure this; e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year. (For example, describe the actions that will be taken to compensate for the reduction in clinic responsibilities of the candidate, e.g., hiring of additional staff). Describe the candidate's academic appointment, bearing in mind that it must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary should not be contingent upon the receipt of this award. Describe the proportion of time currently available for the candidate's research experience and what the candidate's institutional responsibilities will be if an award is made.
- b. Provide the candidate with appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed Research Plan.
- c. Provide appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan.

#### Signatures

The institutional commitment must be dated and signed by the person who is authorized to commit the institution to the agreements and assurances listed above. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the

end of the statement. If the candidate will be working away from the home institution, signatures from both the home and the host institution are required.

The sponsoring institution, through its signatures on the Face Page and in the institutional commitment section, certifies that all items outlined above will be provided and that the institution will abide by the applicable assurances and PHS policies.

## 7.5.4 Research Plan

A Research Plan is required for all types of individual K awards. The Research Plan is a major component of the research career development plan. It is important to relate the research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to achieve the objectives of the career development plan and launch and conduct an independent research career, or enhance an established research career. For mentored K awards, explain the relationship between the candidate's research on the CDA and the mentor's ongoing research program.

For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim; a discussion of possible problems and how they will be managed; and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

The Research Plan should be appropriate for, and tailored to the experience level of the candidate, and allow him/her to develop the necessary skills needed for further career advancement. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are usually not appropriate for the purposes of a CDA. Although candidates for mentored K awards are expected to write the Research Plan, the mentor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful.

**Note: Follow the Research Plan format and instructions described in [Section 5.5. Content of Research Plan](#) except as noted below.**

### 1. Introduction to Resubmission Application

*There is no time limit for the submission of the first and second resubmissions (A1 and A2). See NIH Notice [NOT-OD-07-015](#) for additional information/clarification of NIH policy.*

Resubmission applications must include an Introduction to Resubmission Application, not to exceed three pages. The Introduction must include responses to the criticisms and issues raised in the Summary Statement. Summarize the substantial additions, deletions, and changes. In the body of the application, highlight paragraphs with significant changes by bracketing and changing typography.

### 2. Specific Aims

### 3. Background and Significance

### 4. Preliminary Studies/Progress Report

### 5. Research Design and Methods

**Note: The total number of pages for Section 7.5.1 (The Candidate) and items 2-5 of Section 7.5.4 (Research Plan: this Section) combined may not exceed 25 pages. In many cases, CDA applications will be shorter than the limit.**

Although it is understood that CDA applications do not require the extensive detail usually incorporated into regular research applications, a fundamentally sound Research Plan and a reasonably detailed methods section should be provided.

In general, less detail will be expected in descriptions of research planned for the future years of the proposed CDA. However, there should be sufficient detail to enable the peer reviewers to determine that the plans for those years, including the methods to be used, are appropriate and are likely to enable the candidate to achieve the objectives of the Research Plan.

6. **Inclusion Enrollment Report (Renewal Applications only)**
7. **Bibliography and References Cited/Progress Report Publication List**
8. **Protection of Human Subjects**
9. **Inclusion of Women and Minorities**
10. **Targeted/Planned Enrollment Table**
11. **Inclusion of Children**
12. **Vertebrate Animals**
13. **Select Agents**
14. **Multiple PD/PI Leadership Plan (Not applicable to CDAs)**
15. **Consortium/Contractual Arrangements**
16. **Letters of Support/Consultants (Not applicable to CDAs, see [Part I, 7.5.2](#))**
17. **Resource Sharing Plan(s)**

### 7.5.5 Checklist

[CHECKLIST FORM PAGE](#)

**Submit the Checklist Page with the application.**

#### **Type of Application**

Check all that apply.

#### **Inventions and Patents (Renewal Applications Only)**

If no inventions were conceived or reduced to practice during the course of work under this project, check “No.” The remaining parts of the item are then not applicable.

If any inventions were conceived or reduced to practice during the previous period of support, check “Yes.” Also indicate whether this information has been reported previously to the PHS or to the applicant organization official responsible for patent matters.

**Note:** NIH recipient organizations must promptly report inventions to the Extramural Inventions and Technology Resources Branch of the Office of Policy for Extramural Research Administration, OER, NIH, Bethesda, MD 20892-2750, (301) 435-1986. Invention reporting compliance according to regulations at 37 CFR 401.14 is described at <http://www.iedison.gov>. The grantee is encouraged to submit reports electronically using Interagency Edison (<http://www.iedison.gov>). See also “[Inventions and Patents](#)” in the *Policies, Assurances and Definitions and Other Information*.

#### **Program Income**

If no program income is anticipated during the period(s) for which grant support is requested, so state.

If program income is anticipated, use the format provided. If the application is funded, the Notice of Award will provide specific instructions regarding the use of such income.

### **Assurances/Certifications**

Each application to the PHS requires that the policies, assurances, and certifications listed on the Checklist be verified by the signature of the official signing for the applicant organization on the Face Page of the application.

### **Facilities and Administrative (F&A) Costs**

For career awards other than the R00 phase of the K99/R00, these costs will be reimbursed at 8 percent of modified total direct costs.

### **7.5.6 Appendix**

Follow the instructions in [Section 5.7](#).



## 8. Instructions for Preparing an Institutional Research Training Application Including Ruth L. Kirschstein-NRSA Applications

### Sequential Guide for Preparing an Institutional Training Grant Application Including Ruth L. Kirschstein-NRSA Applications (Requires use of Part I, Sections 4 and 8)

WEB DOCUMENT LINKS	PART I
<b>Form Page 1</b> , Item 1. PHS 398 Instructions	<a href="#">4.1</a>
<b>Form Page 1</b> , Item 2. Institutional Training Grant Instructions and PHS 398 Instructions	<a href="#">8.2</a> <a href="#">4.1</a>
<b>Form Page 1</b> , Item 3. PHS 398 Instructions	<a href="#">4.1</a>
<b>Form Page 1</b> , Item 4. Institutional Training Grant Instructions	<a href="#">8.2</a>
<b>Form Page 1</b> , Item 5. Institutional Training Grant Instructions	<a href="#">8.2</a>
<b>Form Page 1</b> , Item 6. Institutional Training Grant Instructions and PHS 398 Instructions	<a href="#">8.2</a> and <a href="#">4.1</a>
<b>Form Page 1</b> , Item 7. PHS 398 Instructions	<a href="#">4.1</a>
<b>Form Page 2 and Institutional Training Substitute Form Page 3:</b> Institutional Training Grant Instructions (Form Page 2 and Substitute Form Page 3)	<a href="#">8.3</a> and <a href="#">8.4</a>
<b>Institutional Training Substitute Form Page 4:</b> Institutional Training Grant Instructions and Stipends	<a href="#">8.5</a>
<b>Institutional Training Substitute Form Page 5:</b> Institutional Training Grant Instructions	<a href="#">8.6</a>
<b>Biographical Sketch Format Page:</b> Institutional Training Grant Instructions	<a href="#">8.7</a>
<b>Resources Format Page:</b> Institutional Training Grant Instructions	<a href="#">8.8</a>
<b>Research Training Program Plan:</b> Institutional Training Grant Instructions	<a href="#">8.9</a>

### 8.1. Introduction

This section includes instructions to be used when applying for competing (New, Renewal, Resubmission or Revision) institutional training grants, including both PHS Institutional Ruth L. Kirschstein National Research Service Awards (Kirschstein-NRSA) and non-NRSA awards. The contents include substitute form pages for the Table of Contents and both budget pages, and instructions for the Research Training Program Plan. Begin by reading the previous Sections 4 and 5, and then follow both sets of instructions using the Sequential Guide for Preparing an Institutional Training Grant Application (see table above).

Prior to preparing an application, review the Funding Opportunity Announcement (FOA) to which you are responding and consult with the appropriate [PHS awarding component](#) identified in the FOA. Current NIH-wide T32, T34 or T35 Kirschstein-NRSA Program Announcements (PA) are available at (<http://grants.nih.gov/training/nrsa.htm>). Note especially the eligibility requirements, submission dates, award provisions, payback provisions, and review criteria. PAs are also issued periodically by the individual NIH Institutes or Centers in the [NIH Guide for Grants and Contracts](#). These training programs may or may not be Kirschstein-NRSA award programs. Non-NRSA programs may have different eligibility requirements, submission dates, award provisions, and review criteria. This information is available from the appropriate PHS agency, from grantee offices of sponsored programs, or equivalent offices.

**Please note that for Kirschstein-NRSA programs that include postdoctoral trainees, the Program Director must explain the terms of the payback service requirement to all prospective postdoctoral training candidates. A complete description of the service payback obligation is available in the relevant NRSA Program Announcement or the [NIH Grants Policy Statement](#).**

## 8.2 Specific Instructions

### 8.2.1 Face Page

**Complete as directed in the previous Section 4, except items 2, 4, 5, and 6, which are to be completed in accordance with the following instructions:**

#### **Item 2. Response to Specific Request for Applications (RFA) or Program Announcement (PA)**

Enter the specific FOA number and title, such as PA-06-468 "Ruth L. Kirschstein NRSA Institutional Research Training Grant."

#### **Item 4. Human Subjects Research**

Check "Yes" if training plans include or potentially will include trainee participation in projects involving human subjects as defined by 45 CFR 46 (see Part III, Human Subjects Research Definitions and Terms, and Part I, 4.1, Item 4 for additional guidance concerning the involvement of human subjects). If training plans are not anticipated to involve human subjects, check "No" and leave the remaining items 4a-4d blank. If plans for research involving human subjects are indefinite at the time of application, check "yes" and provide an explanation in the Research Training Program Plan at 8.9.7.

**4a.** If human subjects will be involved, but the proposed research meets the criteria for one or more exempt categories described in the DHHS regulations for the protection of human subjects (45 CFR 46); check "yes" and enter the exemption number(s) corresponding to one or more of the six exemption categories listed in Part III.3 under Human Subjects Research Definitions and Terms (See [Exemption Categories](#)). Check "no" if activities will, or potentially will, involve human subjects and are *not* anticipated to meet the criteria for research that is exempt from regulatory requirements, and complete the remaining parts of Item 4.

The institution must ensure that trainees who will be involved in the design or conduct of research involving human subjects receive training in human subjects protections. It is the institution's responsibility to ensure that trainees are properly supervised when working with human subjects.

**4b.** If the applicant organization has a current approved Federal Wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), enter the number in Item 4b. Enter "none" if the applicant organization does not have an approved assurance on file with OHRP. Do not enter the FWA number of any institution other than the applicant organization.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IRB approval or a determination of exemption exists. Existing IRB approval is sufficient for trainees, provided that the IRB determines the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB approval dates or exemption designation in Section 8.9.7 of the Research Training Program Plan.

If an award is made and the research is not exempt from requirements stipulated in 45 CFR 46, and trainees will participate in research for which IRB review and approval does not otherwise exist, human subjects may **not** be involved and trainees may **not** participate in research involving human subjects unless the engaged institution has an approved FWA on file with OHRP, certification of the date of IRB approval has been submitted to and accepted by the PHS agency, and NIH requirements for human subjects protections have been addressed (see instructions in [Part II, Preparing the Protection of Human Subjects Section of the Research Plan](#), and in the Research Training Program Plan at 8.9.7).

**4c.** If training plans include, or potentially will include, trainee participation in a project defined as a Clinical Trial, answer “Yes” to question 4c.

**4d.** If training plans include or potentially will include trainee participation in projects that are NIH-Defined Phase III Clinical Trials, answer “Yes” to question 4d.

Inclusion and Population Tracking reporting requirements do not apply to training grants.

These policies apply to all Project/Performance Sites.

## **Item 5. Vertebrate Animals**

Check “Yes” if training plans include or potentially will include trainees in projects involving the use of live vertebrate animals at any time during the proposed project period, either at the applicant organization or at any other training site or collaborating institution. If training plans are not anticipated to involve vertebrate animals, check “No” and leave item 5a blank. Note that generation of custom antibodies constitutes an activity involving vertebrate animals. If plans to include trainees in vertebrate animal activities are indefinite at the time of application, check “Yes,” provide an explanation in the Research Training Program Plan at Section 8.9.8, and indicate when it is anticipated that animals will be used.

The institution must ensure that trainees are enrolled in the institution’s animal welfare training and occupational health and safety programs for personnel who will have contact with animals. It is the institution’s responsibility to ensure that trainees are properly supervised when working with live vertebrate animals.

These policies apply to all training sites.

**5a.** If the applicant organization has a current approved Animal Welfare Assurance (Assurance) on file with the Office of Laboratory Animal Welfare (OLAW), enter the number in Item 5a. Contact the IACUC to determine whether the organization currently has an approved Assurance. Alternatively, this information may be obtained at the following website:

<http://grants.nih.gov/grants/olaw/olaw.htm#assur>. Enter “none” if the applicant organization does not have an approved Assurance on file with OLAW. Do not enter the Assurance number of any institution other than the applicant organization. Submission of the application constitutes declaration that the applicant organization will comply with the [PHS Policy on Humane Care and Use of Laboratory Animals](#) by submitting an Assurance when request by OLAW and providing verification of IACUC approval when requested by the PHS awarding component.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IACUC review and approval exists. This existing IACUC approval is sufficient for trainees, provided that the research would not be substantially

modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC approval dates in Section 8.9.8 of the Research Training Program Plan.

If an award is made and trainees will participate in research for which IAUC approval does not otherwise exist, vertebrate animals may **not** be involved and trainees may **not** participate in research utilizing vertebrate animals unless the institution has an approved Assurance on file with OLAW, certification of the date of IACUC approval has been submitted to and accepted by the PHS agency, and NIH requirements for the use of vertebrate animals have been addressed (see instructions at 5.5 item 12).

#### **Item 6. Dates of Entire Proposed Period of Support**

The usual starting date for an institutional Kirschstein-NRSA is July 1, but there are other possible starting dates. Consult the webpage of Standard Due Dates for Competing Applications (<http://grants.nih.gov/grants/funding/submissionschedule.htm>). Many PHS awarding components restrict submission and review dates to once a year. Applicants are strongly encouraged to contact the appropriate awarding component staff before submitting an application.

### **8.3 Description, Project/Performance Sites, Senior/key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells**

#### [FORM PAGE 2](#)

#### **Description: Project Summary and Relevance**

The first and major component of the Description is a **Project Summary**. Summarize the objectives, rationale and design of the research training program. Provide information regarding the research areas and scientific disciplines encompassed by the program. Include a brief description of the level(s) and duration of the proposed training, the projected number of participating trainees and their anticipated levels of experience.

The second component of the Description is **Relevance**. Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

#### **Project/Performance Sites.**

List all of the locations where training, program management, and the research experiences described in the Research Training Program Plan (8.9) will be performed. If a Project/Performance Site will be engaged in research involving human subjects, it is the responsibility of the applicant organization to assure that all Project/Performance Sites comply with the human subject protection regulations in [45 CFR Part 46](#) and NIH policies for the protection of human subjects. For research involving live vertebrate animals, the applicant organization must supply information for all training sites where animals will be used by trainees. The applicant organization is responsible for assuring that all Project/Performance Sites have a current Animal Welfare Assurance and comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

#### **Senior/key Personnel and Other Significant Contributors.**

The Program Director, training faculty and any other individuals whose contributions are critical to the development, management and execution of the Research Training Program Plan in a substantive, measurable way (whether or not salaries are reimbursed) should be identified as Senior/key Personnel. Since these efforts are not project related research endeavors, they should not be identified in Other Support information. The Other Significant Contributors section is not relevant for institutional training grant and NRSA applications.

**Human Embryonic Stem Cells (HESC).** For each trainee utilizing HESC in a research project, list project title, mentor, and specific cell line(s) from the [registry](#).

## 8.4 Table of Contents

### [INSTITUTIONAL TRAINING GRANT SUBSTITUTE FORM PAGE 3](#)

Use the substitute Table of Contents for all Kirschstein-NRSA training grant applications. See instructions in the FOA to which you are responding for which form to use for non-NRSA applications.

Provide the page number for each category listed on the Table of Contents. Place page numbers at the bottom of each page, and consecutively number pages throughout the application. Do not include unnumbered pages, and do not use suffixes, such as 5a, 5b.

## 8.5 Detailed Budget for Initial Budget Period

### [INSTITUTIONAL TRAINING GRANT SUBSTITUTE FORM PAGE 4](#)

If you are requesting a budget of \$500,000 direct costs or more for any year, contact the awarding component to determine whether you must obtain prior approval before submitting the application. (See [Policy on the Acceptance for Review of Unsolicited Applications That Request \\$500,000 or More in Direct Costs.](#))

Complete the Institutional Training Grant Substitute Form Page 4 following the instructions below. Refer to the relevant PA or consult the PHS awarding component for current allowable costs and stipend levels. Additional details will be provided on Institutional Training Grant Substitute Form Page 5. For non-NRSA training grant programs refer to the FOA for instructions regarding which Budget Form pages to use and how to complete them.

### Stipends

Enter the number of trainees and total stipend amount for each trainee category as appropriate. For Kirschstein-NRSA applications, use the current Institutional [Kirschstein-NRSA Stipends Notice](#), published in the NIH Guide and listed under NRSA Policy Issues at <http://grants.nih.gov/training/nrsa.htm>. If a category contains different stipend levels, e.g., for varying levels of postdoctoral experience and/or varying appointment periods, itemize. Enter the total stipends for all categories in the Dollar Total column.

### Tuition and Fees

Institutions are referred to the policy for funding of tuition, fees, and health insurance, [NOT-OD-06-093](#). Note that health insurance is not included as part of this budget category. See the Training Related Expenses category below.

Explain, in detail, the composition of tuition and fees and itemize them individually. If tuition varies, (e.g., in-state, out-of-state, student status) identify these separately. Tuition at the postdoctoral level is limited to that required for specified courses. Tuition and fees may be requested only to the extent that the same resident or nonresident tuition and fees are charged to non-Federally supported students and postdoctorate fellows. Applicants should request full needs. Enter the total requested in the Dollar Total Column. A formula will be applied by the NIH awarding component at the time an award is calculated.

### Trainee Travel

State the purpose of any travel, giving the number of trips involved, the destinations, and the number of trainees for whom funds are requested. PHS policy requires coach class air travel be used. Justify

foreign travel in detail, describing its importance to the training experience. Enter the total requested in the Dollar Total Column.

### **Training Related Expenses (including Health Insurance)**

Funds to defray other costs of training, such as health insurance (self-only or family), staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the amounts for each predoctoral and postdoctoral trainee specified in the relevant FOA. Enter the number of positions requested (predoctoral, postdoctoral, short-term), multiply each by the relevant Training Related Expenses level in the [NRSA Stipends Notice](#), and enter the sum under Dollar Total.

Health insurance (self-only or family, as applicable) is an allowable expense that may be charged to the Training Related Expenses budget category but only to the extent that the same health insurance fees are charged to non-Federally-supported students and postdoctoral fellows. See [NOT-OD-06-093](#) for details.

No further itemization or explanation of the Training Related Expenses budget category is required.

The awarding Institute/Center will apply the Training Related Expenses level established in the [NRSA Stipends Notice](#) for the relevant fiscal year at the time of award.

## **8.6 Budget for Entire Proposed Period of Support**

[INSTITUTIONAL TRAINING GRANT SUBSTITUTE FORM PAGE 5](#)

Use the Institutional Training Grant Substitute Form Page 5.

## **8.7 Biographical Sketch**

[BIOGRAPHICAL SKETCH FORMAT PAGE](#)

There is no Form Page for biographical sketches. Follow the format on the Biographical Sketch Format Page. Include biographical sketches, not to exceed four pages each, for the Program Director and Other Senior/key Personnel contributing to the training program. Assemble sketches with the Program Director first and others following in alphabetical order. See instructions in 4.6. Biographical sketches for mentors will be provided in 8.9.13 below.

The Program Director must be registered in the eRA Commons and must include the assigned Commons User ID.

## **8.8 Resources**

[RESOURCES FORMAT PAGE](#)

Follow the format and instructions on the Resources Format Page. Describe the facilities and resources that will be used in the proposed training program. Indicate in what ways the applicant organization will support the program (e.g., supplementation of stipends, protected time for mentoring, support for student activities).

## **8.9 Research Training Program Plan**

**Before preparing the training plan, be sure to check the specific instructions in the Funding Opportunity Announcement (FOA) to which you are responding. Contact the appropriate PHS awarding component, which may have further advice or suggestions on completing your application, including the data tables mentioned below.**

Note that there are page limits for certain sections. Sections 8.9.2-8.9.5, collectively, may **not** exceed 25 pages. Sections 8.9.6-8.9.15 are not part of the 25 page limitation. The information provided in required data tables (see below) will not be counted toward the page limitation. These tables should be numbered consecutively and titled as shown, even if some are not required by the PHS awarding component to which you are applying or in the FOA to which you are responding. Indicate by table number and title, those tables that are intentionally omitted. Additional tables that are not required may be included in the Research Training Program Plan, however, these tables will count as part of the 25 page limit. Additional tables not specified in these instructions should be identified by letter, rather than number to avoid confusion with the sequentially numbered required tables.

The instructions for Data Tables 1-12 are located on the OER website at <http://grants.nih.gov/grants/funding/phs398/phs398.html#DataTableInstruct>. Please read the [Introduction to the Data Tables](#) in Section 8.9.14 before beginning to prepare your application. This section includes important definitions that should be used consistently both in the Data Tables and in all other parts of the application. The tables described in Section 8.9.14 should be included in the application at the point indicated and should not be inserted in the narrative for Sections 8.9.2-8.9.5.

### 8.9.1 Introduction (Resubmission or Revision Applications Only)

If you are preparing a Resubmission or Revision application, prepare an Introduction section. The Introduction may not exceed three pages for Resubmission applications or one page for Revision applications. See specific instructions in Section 2.7 Resubmission Applications and 2.8 Revision Applications concerning the content of the Introduction.

### 8.9.2 Background

Provide the rationale for the proposed research training program, relevant background history, and the need for the research training proposed. Indicate how the proposed program relates to current training activities at the applicant institution.

Summarize the research training activities of the major participating unit(s) and department(s) represented in the proposed program. Complete and refer to the data reported in Tables 1-3:

[Table 1](#). Membership of Participating Departments/Programs

[Table 2](#). Participating Faculty Members

[Table 3](#). Institutional Training Grant Support Available to Participating Faculty Members, Departments, or Programs

Use this data to document the environment in which the proposed training program will take place.

### 8.9.3 Program Plan

**a. Program Administration.** Describe the Program Director's qualifications for providing leadership of the program, including relevant scientific background, current research areas, and experience in research training. Indicate the Program Director's percent effort in the proposed program.

Describe the administrative structure of the program and the distribution of responsibilities within it, including the means by which the program director will obtain continuing advice with respect to the operation of the program.

Multiple Program Directors may be proposed **only** if the FOA to which you are responding indicates that multi-PD applications will be accepted. If multi-PDs are proposed, explain in this section your rationale for how this will facilitate program administration. In addition, you must complete Section 8.9.11 Multiple-PD Leadership Plan.

**b. Program Faculty.** Refer to the data presented in [Table 2. Participating Faculty Members](#) and elaborate as necessary to describe each faculty member's research that is relevant to the program and indicate how trainees will participate in the research. Describe the extent to which participating faculty members cooperated, interacted, and collaborated in the past, including joint publications and joint sponsorship of student research. Complete and refer to data in Tables 4-6:

[Table 4.](#) Grant and Contract Support of the Participating Faculty Members

[Table 5.](#) Pre and Postdoctoral Trainees of Participating Faculty Members

[Table 6](#) Publications of Research Completed by Trainees (or Potential Trainees)

Use these tables to document the ability of the faculty to support the research activities of the proposed trainees, the training record of the faculty members, and the success of their trainees in generating publishable research results.

For new applications, see the instructions for Table 6 in Section 8.9.14 and list publications for trainees who are representative of those who would be appointed if the grant is awarded. For Renewal applications, this data constitutes part of the Progress Report (see Section 8.9.6 Progress Report below).

**c. Proposed Training.** Describe the proposed training program. State the training level and number of trainees. For postdoctoral trainees, indicate the proposed distribution by degree (e.g., M.D., Ph.D.). Describe course work and research opportunities, the extent to which trainees will participate directly in research, and the duration of training, i.e., usual period of time required to complete the training offered.

Indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated and how they will relate to an individual trainee's experience.

For training programs that emphasize research training for clinicians, describe the interactions with basic science departments and scientists. Include plans for ensuring that the training of these individuals will provide a substantive foundation for a competitive research career. Generally, a minimum of 2 years of research training is required for all postdoctoral trainees with health professional degrees. Describe fully any trainee's access to and responsibility for patients, including time commitment.

Provide representative examples of programs for individual trainees. Include curricula, degree requirements, didactic courses, laboratory experiences, qualifying examinations, and other training activities, such as seminars, journal clubs, etc. Describe how the preceptor and research problems are chosen, how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated. Include detailed mentoring plans as appropriate.

**d. Training Program Evaluation.** Program directors are encouraged to develop methods for ongoing evaluation of the quality of the training program. Describe any plans for such an evaluation, e.g., plans to obtain feedback from current and former trainees to help identify weaknesses in the training program and to provide suggestions for program improvements.

**e. Trainee Candidates.** Describe recruitment plans, including the sources and availability of trainees; the qualifications of prospective trainees; and the criteria and procedures by which trainees will be selected.

## **Admissions and Completion Records**

For programs that request only predoctoral trainee support, complete [Table 7A](#). Admissions and Completion Records for the Participating Departments and Programs During the Past Five Years (Predoctoral Applicants).



For programs that request only postdoctoral trainee support, complete [Table 7B](#). Admissions and Completion Records for the Participating Departments and Programs During the Past Five Years (Postdoctoral Applicants).

Programs requesting support for both predoctoral and postdoctoral trainees need to complete both [Table 7A](#) and [Table 7B](#).

Use these tables to document the ability of the participating departments/programs to recruit and retain predoctoral and/or postdoctoral trainees through the completion of their training, the selectivity of the admissions process, the success of the departments/programs in recruitment and retention of trainees from diverse backgrounds, and to defend the requested number of training positions to be awarded.

### **Qualifications of Applicants**

For programs that request only predoctoral trainee support, complete [Table 8A](#). Qualifications of Recent Predoctoral Applicants.

For programs that request only postdoctoral trainee support, complete [Table 8B](#). Qualifications of Recent Postdoctoral Applicants.

Programs requesting support for both predoctoral and postdoctoral trainees need to complete both [Table 8A](#) and [Table 8B](#).

Use these tables to document the quality and depth of the applicant pools, including both Kirschstein-NRSA training grant eligible and non-Kirschstein-NRSA eligible applicants; the selectivity of the admissions process; the competitiveness of the program; and to justify the number of number of training positions requested.

### **Current Trainee Qualifications**

For programs that request only predoctoral trainee support, complete [Table 9A](#). Qualifications of the Current Predoctoral Trainees Clearly Associated with the Training Program.

For programs that request only postdoctoral trainee support, complete [Table 9B](#). Qualifications of the Current Postdoctoral Trainees Clearly Associated with the Training Program.

Programs that request both predoctoral and postdoctoral trainee support need to complete both [Table 9A](#) and [Table 9B](#).

Use these tables to document the number and quality of all trainees currently enrolled in the program, and their distribution by department and mentor; the selectivity of enrollment appointments to the training grant over the time period represented by the current program participants; and to defend the number of training positions to be awarded.

## **8.9.4 Recruitment and Retention Plan to Enhance Diversity**

The NIH recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences workforce. The NIH expects efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; to improve the quality of the educational and training environment; to balance and broaden the perspective in setting research priorities; to improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and to improve the Nation's capacity to address and eliminate health disparities.

Accordingly the NIH continues to encourage institutions to diversify their student and faculty populations and thus to increase the participation of individuals currently underrepresented in the biomedical, clinical, behavioral, and social sciences such as: individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in

health-related research. Institutions are encouraged to identify candidates who will increase diversity on a national or institutional basis.

### **Definition of Diversity Recruitment Groups**

The NIH is particularly interested in encouraging the recruitment and retention of the following classes of candidates:

A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see data at <http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27> and the report Women, Minorities, and Persons with Disabilities in Science and Engineering, 2007, p. 262). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: African Americans, Hispanic Americans, Native Americans, Alaskan Natives, Hawaiian Natives, and natives of the US Pacific Islands. In addition, it is recognized that under-representation can vary from setting to setting and individuals from racial or ethnic groups that can be convincingly demonstrated to be underrepresented by the grantee institution should be included in the recruitment and retention plan.

B. Individuals with disabilities, who are defined as those with a physical or mental impairment that substantially limits one or more major life activities.

C. Individuals from disadvantaged backgrounds who are defined as:

1. Individuals who come from a family with an annual income below established low-income thresholds. These thresholds are based on family size, published by the U.S. Bureau of the Census; adjusted annually for changes in the Consumer Price Index; and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels at <http://aspe.hhs.gov/poverty/index.shtml>. For individuals from low income backgrounds, the institution must be able to demonstrate that such candidates (a) have qualified for Federal disadvantaged assistance; or (b) have received any of the following student loans: Health Professional Student Loans (HPSL), Loans for Disadvantaged Student Program; or have received scholarships from the U.S. Department of Health and Human Services under the Scholarship for Individuals with Exceptional Financial Need.

2. Individuals who come from a social, cultural, or educational environment such as that found in certain rural or inner-city environments that have demonstrably and recently directly inhibited the individual from obtaining the knowledge, skills, and abilities necessary to develop and participate in a research career. Recruitment and retention plans related to a disadvantaged background are most applicable to high school and perhaps undergraduate candidates, but would be more difficult to justify for individuals beyond that level of achievement.

**New applications** must include a description of plans to enhance recruitment of a diverse trainee pool and may wish to include data in support of past accomplishments. **Renewal applications** must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous funding period. Information should be included on both successful and unsuccessful recruitment strategies.

**History and Achievements.** Describe efforts to recruit trainees from Diversity groups A, B, and C into the existing training program. For competing continuation/renewal applications, also describe past efforts to recruit and retain underrepresented minority students into training grant funded positions. Refer to the data presented in [Table 1](#) and [Tables 7A](#) and [Table 7B](#) that provided statistics on applications and admissions of these groups in comparison to the overall trainee pool.

For Renewal applications, complete [Table 10](#) Admissions and Completion Records for Underrepresented Minority (URM), Trainees with Disabilities, and Trainees from Disadvantaged Backgrounds Clearly Associated with the Training Program. New applicants may provide this data if they wish; however, it is not required of new applicants.

Use this data to document the success of the program in recruiting and retaining trainees who are under-represented minorities, provide analysis of their support, and begin to establish a record of NIH training of other Diversity Recruitment groups.

**Proposed plans.** Describe steps to be taken during the proposed award period regarding the identification, recruitment, and retention of graduate students and postdoctorates from underrepresented groups. Consider the success and/or failures of recruitment strategies used in the past. In particular, describe the specific efforts to be undertaken by the training program and how these might relate to the recruitment efforts of the medical school, graduate school, and/or the university at large. In most cases, institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups.

Applications without a description of diversity recruitment efforts will be considered incomplete and may be delayed in the peer review process.

### 8.9.5 Plan for Instruction in the Responsible Conduct of Research

Every trainee **must** receive instruction in the responsible conduct of research. Describe a plan to provide trainees with formal and informal instruction on scientific integrity and ethical principles in research. The plan must address the rationale for the instruction, the format and subject matter, the degree of faculty participation, trainee attendance, plans to assess the quality and the frequency of instruction. For Renewal applications, describe the type of instruction provided in the current project period, the degree of student participation, the results of any assessments and other relevant information.

There are no specific curriculum or format requirements for this instruction; however, it is strongly suggested that the instruction include: conflict of interest, responsible authorship and publication, peer review, policies for handling misconduct, policies regarding human subjects and live vertebrate animal subjects in research, data management, data-sharing, collaborative research and mentor-mentee relationships. Applicants may wish to consult the NIH web site at <http://grants.nih.gov/training/responsibleconduct.htm> and <http://www.nih.gov/sigs/bioethics/researchethics.html> for additional guidance.

Applications lacking a plan for instruction in the responsible conduct of research will be considered incomplete and will be returned to the applicant without review.

Trainees who will participate in research involving human subjects must meet the NIH policy requirement for education in human subjects protections (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>). Trainees participating in research with live vertebrate animals must also be enrolled in the institutional animal welfare training program for personnel who have contact with animals. The requirements for specific human subjects education and participation in the institutional animal welfare training program may be included as elements of required training in the Responsible Conduct of Research.

### 8.9.6 Progress Report (Renewal Applications Only)

State the period covered and briefly describe the accomplishments of the training program. Describe any specific effects of this training program on curriculum and/or research directions. Describe how the funds provided under Training Related Expenses were used to benefit the program. For each trainee supported during the period covered, indicate their preceptor/mentor, and briefly summarize the research conducted by the trainee. For previous trainees appointed to the training grant and continuing in training, provide a brief statement of their status and progress toward completion of their training program. Refer to data presented in [Table 6](#) Publications of Research Completed by Trainees (or Potential Trainees) and include in the table publications of trainees through the time that they complete their training for all trainees currently or previously supported by the training grant program regardless of whether support from this training grant is cited in the publication.

Complete [Table 11](#) Appointments to the Training Grant For Each Year of the Past Award (Renewal Applications Only).

Use this table to document the utilization of awarded training positions. If any trainee positions were not filled, provide an explanation.

For programs that request only predoctoral trainee support, complete [Table 12A](#) Predoctoral Trainees Supported by this Training Grant (Renewal Applications Only).

For programs that request only postdoctoral trainee support, complete [Table 12B](#) Postdoctoral Trainees Supported by this Training Grant (Renewal Applications Only).

Programs requesting support (or reporting on prior support) for both predoctoral and postdoctoral trainees need to complete both [Table 12A](#) and [Table 12B](#).

Use these tables to document how predoctoral training positions are used (i.e., distribution by mentor, year in program, years of support per trainee) and the success of the program in achieving the training objectives of the prior award period(s) for up to 10 years. Summarize this data in the text.

If any postdoctoral trainee with a health professional degree appointed to the grant during the most recent award period received less than 2 years of research training, explain why. Where possible for past trainees, describe the extent of their current involvement in research, including research grant support and representative recent publications. Use the progress report narrative to provide information that is not readily presented in the required tables.

### **8.9.7 Human Subjects**

If trainee participation in research involving human subjects is solely as part of other research projects that have received or will receive IRB review and approval, and no portion of the Training Grant Award will be used to support this research; provide a list of previously approved research projects (grant number, PD/PI, and project title) and their IRB approval dates or exemption designations. If plans are indefinite provide an explanation and prior to trainee participation in other research project grants, provide a list as indicated.

If the training program involves definite plans for the participation of human subjects as defined in Part III.3, Human Subjects Research Definitions and Terms, outside of research projects that have received or will receive IRB review, follow the instructions in [Part II, Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan](#).

### **8.9.8 Vertebrate Animals**

If the training program involves the use of live vertebrate animals solely as part of other research project grants, and no portion of the Training Grant Award will be used to support the purchase, use, or husbandry of live vertebrate animals in this research; provide a list of previously approved research projects (grant number, PD/PI, and project title) and IACUC approval dates. If plans are indefinite provide an explanation and prior to trainee participation in other research project grants, provide a list as indicated.

If the training program involves definite plans to use live vertebrate animals outside of research projects that have received or will receive IACUC approval, follow the instructions in Part I, 5.5, Item 12. [Vertebrate Animals](#).

### **8.9.9 Select Agent Research**

If participating faculty proposed in the training program are conducting or plan to conduct research involving select agents in which trainees *may* participate, follow the instructions in Section 5.5, Item 13. [Select Agents](#).

## 8.9.10 Literature Cited

Follow the instructions in Section 5.5, Item 7a, [Bibliography and References Cited](#). Include here references to literature cited in the Research Training Plan, such as articles and reviews dealing with the scientific area of training, pedagogical concepts, or evaluation methods. Do not include here publications of the faculty or trainees that are not otherwise cited in the text. These should be reported in the requested Data Tables.

## 8.9.11 Multiple PD Leadership Plan

If the specific FOA to which you are responding indicates that multi-Program Director applications will be accepted, and you wish to submit a multi-PD application, you must provide a Leadership Plan. Refer to the instructions in Section 5.5, item 14. Multiple PD/PI Leadership Plan. However, the emphasis in a training grant multiple PD leadership plan should be on how it will benefit the program and the trainees. A single Contact PD must be designated for the purpose of communicating with the NIH, although other individuals may contact the NIH on behalf of the Contact PD when necessary. Because training programs are intended to be coherent, NIH will not allocate the budget or training positions between multiple PDs. A single award will be made. Multiple PD plans should include reasonable numbers of PDs and each should be included for a specific purpose. Multiple-PD applications should **not** include all mentors of the training grant as PDs, except in unusual cases.

For background information on the Multi-PD/PI initiative, see:  
[http://grants.nih.gov/grants/multi\\_pi/index.htm](http://grants.nih.gov/grants/multi_pi/index.htm).

## 8.9.12 Consortium/Contractual Arrangements

Describe any programmatic, fiscal, or administrative arrangements between the applicant organization and other participating organizations. See [Section 5.5, Item 15, Consortium/Contractual Arrangements](#) for additional guidance

## 8.9.13 Participating Faculty Biosketches

Faculty Biosketches for all mentors involved in large programs may be included at this point in the application. The Biosketches of the Program Director and other Senior/key Personnel should be included after the Budget Pages.

## 8.9.14 Data Tables

Instructions for Data Tables 1-12 mentioned above are located on the OER website at the following URL <http://grants.nih.gov/grants/funding/phs398/phs398.html#DataTableInstruct>. These instructions include an [Introduction to the Data Tables](#) that provides instructions applicable to all tables, specific instructions for each table, and [Sample Data Tables](#). The Sample Data Tables illustrate the kind of data to include in each table for Kirschstein-NRSA training grant applications. This webpage also includes an explanation of how this information is used by reviewers and NIH staff during peer review and in reaching funding decisions. Blank Data Tables are available to download. Modification of these instructions for use in non-Kirschstein-NRSA training grant applications will be included in relevant FOAs.

## 8.9.15 Letters of Support

Letters documenting any agreements between the Program Director and senior administration officials or other institutional officials are not required but may be included at this point.

## 8.10 Checklist

CHECKLIST FORM PAGE

### **Inventions and Patents**

Not applicable.

### **Facilities and Administrative Costs**

Facilities and Administrative (F&A) costs under Institutional Kirschstein-NRSAs, other than those issued to state or local government agencies, will be awarded at 8 percent of total allowable direct costs (exclusive of tuition and related fees). Equipment and consortium costs are also excluded from the F&A costs on those training grants, where Training Related Expenses are not calculated and awarded on a lump-sum basis, such as the Minority Access to Research Careers Program (MARC) or Career Opportunities in Research (COR) Undergraduate Research Training Program. State and local government agencies will receive the full F&A cost rate.

## 8.11 Appendix

Unless the FOA to which you are responding provides explicit instructions about Appendix materials that will be accepted, follow the instructions in [Section 5.7 Appendix](#).

## **PART II**

# **Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan**

# 1. Introduction

A Protection of Human Subjects section of the Research Plan is required for all applications submitted using the PHS 398 instructions and forms. The information provided in the section on Protection of Human Subjects should be consistent with the information provided on the face page of the application.

For all research involving human subjects, the Scientific Review Group (SRG) will assess the adequacy of protections for research participants against research risks, and the appropriate inclusion of women, minorities, and children, based on the information provided in the application.

To assist in preparing the section on Protection of Human Subjects, six possible scenarios are provided in Section 2 below. All research projects will fall into one of these six scenarios. Determine which scenario the proposed research falls into, then go to the specific instructions applicable to that scenario in [Section 3](#). Where appropriate, Section 3 provides instructions on addressing the Inclusion of Women and Minorities, the Targeted/Planned Enrollment Table, and the Inclusion of Children (items 9, 10, and 11 of the Research Plan). All definitions related to human subjects research are linked to text found in Part III.3 under Human Subjects Research Definitions and Terms. [Section 5](#) of this Part includes descriptions of and links to the DHHS Human Subjects Protections regulations and NIH policies that apply to clinical research.

## 2. Scenarios

### Scenario A. No Human Subjects Research

If no human subjects research is proposed in the application, you will have designated “No” in Item 4. on the PHS 398 face page, and you should provide an explanation or statement to that effect in the Human Subjects section.

See the [instructions for Scenario A](#).

### Scenario B. Non-Exempt Human Subjects Research

If research involving human subjects is anticipated to take place under the award, you will have designated “Yes” in Item 4 on the PHS 398 face page. In the Protection of Human Subjects section of the Research Plan, you must provide sufficient information for reviewers to determine that the proposed research meets (1) the requirements of the DHHS regulations to protect human subjects from research risks (45 CFR Part 46), and (2) the requirements of NIH policies on inclusion of women, minorities, and children. Research involving a clinical trial will fall under either Scenario E or F below.

See the [instructions for Scenario B](#).

### Scenario C. Exempt Human Subjects Research

If **all** of the proposed research meets the criteria for one or more of the exemptions from the requirements in the DHHS regulations (46.101(b)), “yes” should be designated in item 4 and in item 4a on the PHS 398 face page. In the section on Protection of Human Subjects in the Research Plan, provide a justification for the exemption(s) containing sufficient information about the involvement of the human subjects to allow a determination by peer reviewers and NIH staff that claimed exemption(s) is/are appropriate.

The PHS 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. When in doubt, consult with the Office for Human Research Protections (OHRP), Department of



Health and Human Services by accessing their website <http://www.hhs.gov/ohrp/> for guidance and further information.

The exemptions appear in Part III under [Human Subjects Research Definitions and Terms](#).

See the [instructions for Scenario C](#).

### **Scenario D. Delayed-Onset Human Subjects Research**

If human subjects research is anticipated within the period of the award but plans for involvement of human subjects cannot be described in the application as allowed by the DHHS regulations (45 CFR Part 46.118), you will have designated “Yes” in Item 4. on the PHS 398 face page. In the section on Protection of Human Subjects in the Research Plan, you should either include an explanation of anticipated protections for human subjects or an explanation of why protections cannot be described.

Examples of delayed-onset of human subjects research include:

- Human subjects research is dependent upon the completion of animal or other studies; or
- Human subjects research protocols to be included will undergo an independent decision-making process (often defined by a FOA).

See [instructions for Scenario D](#).

### **Scenario E. Human Subjects Research Involving a Clinical Trial**

If research involving human subjects is anticipated to take place under the award, and you intend to conduct a clinical trial during the project period, you will have designated “Yes” in Item 4 on the PHS 398 face page, “No” in Item 4a on the PHS 398 face page, and “Yes” in Item 4c on the PHS 398 face page.

In the section on Protection of Human Subjects in the Research Plan, you must provide sufficient information for reviewers to determine that the proposed research meets:

- 1) the requirements of the DHHS regulations to protect human subjects from research risks (45 CFR Part 46);
- 2) NIH policy requirements for Data and Safety Monitoring for Clinical Trials;
- 3) the ClinicalTrials.gov requirements if applicable;
- 4) the requirements of NIH policies on inclusion of women, minorities, and children; and
- 5) the requirements of NIH policy on reporting race and ethnicity data for subjects in clinical research.

See [instructions for Scenario E](#).

### **Scenario F. Human Subjects Research Involving an NIH-Defined Phase III Clinical Trial**

If research involving human subjects is anticipated to take place under the award, and you intend to conduct an [NIH-defined Phase III clinical trial](#) during the project period, you will have designated “Yes” in Item 4 on the PHS 398 face page, “No” in Item 4a on the PHS 398 face page, and “Yes” in Item 4d on the PHS 398 face page. In the section on Protection of Human Subjects in the Research Plan, you must provide sufficient information for reviewers to determine that the proposed research meets:

- 1) the requirements of the DHHS regulations to protect human subjects from research risks (45 CFR Part 46);
- 2) NIH policy requirements for Data and Safety Monitoring for Clinical Trials;
- 3) the ClinicalTrials.gov requirements if applicable;

- 4) the requirements of NIH policies on inclusion of women, minorities, and children;
- 5) additional Requirements for NIH-defined Phase III clinical trials; and
- 6) the requirements of NIH policy on reporting race and ethnicity data for subjects in clinical research.

See [instructions for Scenario F](#).

### 3. Instructions for Preparing the Section on Protection of Human Subjects

#### Scenario A. No Human Subjects Research Proposed

##### Criteria

<a href="#">Human Subjects Research</a>	No
<a href="#">Exemption Claimed</a>	No
<a href="#">Clinical Trial</a>	N/A
<a href="#">NIH-Defined Phase III Clinical Trial</a>	N/A

##### Instructions and Required Information

In the application narrative, create a heading labeled “Protection of Human Subjects” and include the following statement below the heading: “No Human Subjects Research is proposed in this application.”

If proposed studies using coded human data or biospecimens do not involve human subjects as described in the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens (<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>), provide an explanation of why the proposed studies do not constitute research involving human subjects.

The explanation could include: a description of the source of the data/biospecimens; the role(s) of providers of the data/biospecimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be ensured.

Research that does not involve intervention or interaction with living individuals, or identifiable private information, is not human subjects research (see Definitions in Part III.3).

Research that only proposes the use of cadaver specimens is not human subjects research because human subjects are defined as “living individuals.” The use of cadaver specimens is not regulated by 45 CFR Part 46, but may be governed by other Federal, State or local laws.

#### Scenario B. Non-Exempt Human Subjects Research

##### Criteria

<a href="#">Human Subjects Research</a>	Yes
<a href="#">Exemption Claimed</a>	No
<a href="#">Clinical Trial</a>	No
<a href="#">NIH-Defined Phase III Clinical Trial</a>	No

## Instructions and Required Information

Although no specific page limitation applies to this section of the application, be succinct.

In the application narrative, create a section entitled “Protection of Human Subjects” and create a subheading for each of the following items.

Follow the instructions that are identified for each of the following topics and provide the information that is requested:

Protections for Human Subjects - [Section 4.1 - 4.1.4](#)

Inclusion of Women and Minorities - [Section 4.2](#)

Targeted/Planned Enrollment Table - [Section 4.3](#)

Inclusion of Children - [Section 4.4](#)

If the research involves collaborating sites, provide the information identified above for each participating site.

## Scenario C: Human Subjects Research Claiming Exemption 1, 2, 3, 4, 5, or 6

### Criteria

<a href="#">Human Subjects Research</a>	Yes
<a href="#">Exemption Claimed</a>	1, 2, 3, 4, 5, or 6
<a href="#">Clinical Trial</a>	Yes or No
<a href="#">NIH-Defined Phase III Clinical Trial</a>	No

## Instructions and Required Information

Although no specific page limitation applies to this section of the application, be succinct. The exemptions appear in Part III under [Human Subjects Research Definitions and Terms](#).

Although the research may be exempt from the DHHS regulatory requirements, it is still research involving human subjects and the application must follow the instructions that are identified for each of the following topics and provide the information that is requested.

In the application narrative, create a heading entitled “Protection of Human Subjects” and include the following statement below the heading: “This Human Subjects Research falls under Exemption(s) ... .”

Follow the instructions that are identified for each of the following topics and provide the information that is requested:

Justification for Claimed Exemption(s):

In this section, identify which exemption(s) (1, 2, 3, 4\*, 5, or 6) you are claiming. Justify why the research meets the criteria for the exemption(s) that you have claimed.

If the research will include a clinical trial, even if exempt, include a Data and Safety Monitoring Plan – [Section 4.1.5](#), and address the ClinicalTrials.gov requirements if applicable – [Section 4.1.6](#).

Inclusion of Women and Minorities - [Section 4.2](#)

Targeted/Planned Enrollment Table - [Section 4.3](#)

Inclusion of Children - [Section 4.4](#)

\*NOTE: If all the proposed research meets the criteria for Exemption 4, then the requirements for inclusion of women and minorities, targeted/planned enrollment table, and inclusion of children, do not need to be addressed.

## Scenario D: Delayed-Onset Human Subjects Research

### Criteria

<a href="#">Human Subjects Research</a>	Yes
<a href="#">Exemption</a>	Yes or No
<a href="#">Clinical Trial</a>	Yes or No
<a href="#">NIH-Defined Phase III Clinical Trial</a>	Yes or No

### Instructions and Required Information

In rare situations, applications are submitted with the knowledge that human subjects will be involved during the period of support, but plans are so indefinite that it is not possible to describe the involvement of human subjects in the application. The kinds of activities that lack definite plans are often institutional awards where the selection of specific projects is the institution's responsibility, research training grants, and projects in which the involvement of human subjects depends upon completion of instruments, animal studies, or purification of compounds.

If the involvement of human subjects is indefinite, create a heading entitled "Protection of Human Subjects" and provide a detailed explanation why it is not possible to develop definite plans at this time. The explanation should be specific and directly related to the Specific Aims in the application. If the involvement of human subjects depends upon information that is not presently available (e.g., completion of instruments, animal studies, purification of compounds), be explicit about the information and the factors affecting the availability of the information. Describe the information that will be necessary in order to develop definite plans for the involvement of human subjects, why that information is not currently available, and when the information is expected to become available during the course of the project.

If an award is made, prior to the involvement of human subjects the grantee must submit to the NIH awarding office for prior approval either (1) detailed information as required in the Research Plan, Protection of Human Subjects (addressing risks to the subjects, adequacy of protection against risks, potential benefits of the proposed research, importance of the knowledge to be gained, and data and safety monitoring plan if applicable) and certification of IRB approval, OR (2) if all of the research meets the criteria for one or more exemptions, identification of which exemption(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate. If the research is not exempt, the request for prior approval must also address the inclusion of women and minorities, the inclusion of children, and provide completed targeted/planned enrollment tables as required in the Research Plan.

Under no circumstance may human subjects be involved in non-exempt research until approval is granted by the awarding entity, and certification of IRB approval has been accepted by the agency.

In the application narrative, create a section entitled Protection of Human Subjects and a subheading for each of the following items. Follow the instructions that are identified for each of the following topics and EITHER provide as much of the information that is requested as possible; OR describe why it is not possible to provide the information due to delayed-onset of human subjects research:

Protection of Human Subjects - [Section 4.1 - 4.1.4](#)

If the research will include a clinical trial, include a Data and Safety Monitoring Plan - [Section 4.1.5](#), and address the ClinicalTrials.gov requirements if applicable – [Section 4.1.6](#).

Inclusion of Women and Minorities - [Section 4.2](#)

Targeted/Planned Enrollment Table - [Section 4.3](#)

Inclusion of Children - [Section 4.4](#)

## Scenario E: Clinical Trial

### Criteria

<a href="#">Human Subjects Research</a>	Yes
<a href="#">Exemption</a>	Yes or No
<a href="#">Clinical Trial</a>	Yes
<a href="#">NIH-Defined Phase III Clinical Trial</a>	No

### Instructions and Required Information

In the application narrative, create a section entitled “Protection of Human Subjects” and include the following statement below the heading: “This Human Subjects Research meets the definition of a clinical trial.” (See definition of "[clinical trial](#)" under Part III.3.) Create a subheading for each of the following items. Follow the instructions that are identified for each of the following topics and provide the information that is requested:

Protection of Human Subjects - [Section 4.1 - 4.1.6](#)

Inclusion of Women and Minorities - [Section 4.2](#)

Targeted/Planned Enrollment Table - [Section 4.3](#)

Inclusion of Children - [Section 4.4](#)

If the research involves collaborating sites, provide the information identified above for each participating site.

## Scenario F: NIH Defined Phase III Clinical Trial

### Criteria

<a href="#">Human Subjects Research:</a>	Yes
<a href="#">Exempt:</a>	No
<a href="#">Clinical Trial:</a>	Yes
<a href="#">NIH-Defined Phase III Clinical Trial:</a>	Yes

### Instructions and Required Information

In the application narrative, create a section entitled “Protection of Human Subjects” and include the following statement below the heading: “This Human Subjects Research involves an NIH-Defined Phase III Clinical Trial.” (See definition of "[NIH defined Phase III Clinical Trial](#)" in Part III.3.)

Create a subheading for each of the following items. Follow the instructions that are identified for each of the following topics and provide the information that is requested:

Protection of Human Subjects - [Section 4.1 - 4.1.6](#)

Inclusion of Women and Minorities - [Section 4.2](#)

Additional Instructions and Requirements when NIH-Defined Phase III Clinical Trials are Proposed - [Section 4.2.1](#)

Targeted/Planned Enrollment Table - [Section 4.3](#)

Inclusion of Children - [Section 4.4](#)

If the research involves collaborating sites, provide the information identified above for each participating site.

## 4. Instructions Pertaining to Non-Exempt Human Subjects Research

In your application narrative, create a section entitled "Protection of Human Subjects." Although no specific page limitation applies to this section of the application, be succinct. Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the protection of human subjects. DHHS regulations and policies governing human subjects research are described and referenced in Section 5 below. Use subheadings to address the issues listed under items 4.1-4.4 below. If your research includes a clinical trial, include a subheading "Data and Safety Monitoring Plan" and follow the instructions in 4.2 below. If your research includes an NIH-Defined Phase III Clinical Trial, follow the additional instructions in 4.2.1 below.

### 4.1 Protection of Human Subjects

#### 4.1.1 Risks to Human Subjects

a. **Human Subjects Involvement and Characteristics**

- Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.

b. **Sources of Materials**

- Describe the research material obtained from living individuals in the form of specimens, records, or data.
- Describe any data that will be collected from human subjects for the project(s) described in the application.
- Indicate who will have access to individually identifiable private information about human subjects.

- Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for the proposed research project.

c. **Potential Risks**

- Describe the potential risks to subjects (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

## 4.1.2 Adequacy of Protection Against Risks

a. **Recruitment and Informed Consent**

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

b. **Protections Against Risk**

- Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
- Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to DHHS regulations, and OHRP guidance:
  - Additional Protections for Pregnant Women, Human Fetuses and Neonates: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb>
  - Additional Protections for Prisoners: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc>  
OHRP Subpart C Guidance: <http://www.hhs.gov/ohrp/policy/index.html#prisoners>
  - Additional Protections for Children: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd>  
OHRP Subpart D Guidance: <http://www.hhs.gov/ohrp/children/>
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a general description of the plan for data and safety monitoring of the research and adverse event reporting to the IRB, the NIH and others, as appropriate, to ensure the safety of subjects.

## 4.1.3 Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

#### 4.1.4 Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

NOTE: Test articles (investigational new drugs, devices, or biologics) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the FDA, and/or the status of requests for an Investigational New Drug (IND) or Investigational Device Exemption (IDE) covering the proposed use of the test article in the Research Plan.

#### 4.1.5 Data and Safety Monitoring Plan

The NIH Data and Safety Monitoring Plan Policy is described and referenced in [Section 5.3](#).

- If the research includes a clinical trial, create a heading entitled "Data and Safety Monitoring Plan."
- Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the funding I/C, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Be succinct. Contact the FDA (<http://www.fda.gov/>) and also see the following websites for more information related to IND and IDE requirements:  
[http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfr312\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr312_01.html) (IND)  
[http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfr812\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html) (IDE)
- The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:
  - a. PD/PI (required)
  - b. Institutional Review Board (IRB) (required)
  - c. Independent individual/safety officer
  - d. Designated medical monitor
  - e. Internal Committee or Board with explicit guidelines
  - f. Data and Safety Monitoring Board (DSMB). NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
- A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>). For additional guidance on creating this Plan, see the above reference.



## 4.1.6 ClinicalTrials.gov Requirements

Public Law 110-85 mandates registration and results reporting of "applicable clinical trials" in ClinicalTrials.gov. Under the statute these trials generally include: (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. Review the statutory definition of applicable clinical trial to identify if registration is required to comply with the law (See [PL 110-85](#), Section 801(a), adding new 42 U.S.C. 282(j)(1)(A)).

NIH encourages registration of ALL trials whether required under the law or not.

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

For new and renewal (competing) applications that include ongoing clinical trials which require registration and results reporting, provide the NCT number/s, Brief Title/s (as defined by ClinicalTrials.gov, see <http://prsinfo.clinicaltrials.gov/>), and the identity of the responsible party (or parties) in the human subjects section of the Research Plan under a section heading entitled ClinicalTrials.gov. The entity responsible for registering is the "responsible party." The statute defines the responsible party as:

(1) the sponsor of the clinical trial (as defined in 21 C.F.R. 50.3) ([http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr\\_2003/aprqr/pdf/21cfr50.3.pdf](http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/aprqr/pdf/21cfr50.3.pdf)), or

(2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that "the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements" for submitting information under the law) ([http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ085.110.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf)). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

If a new applicable trial is proposed, under the heading ClinicalTrials.gov include a statement that the application includes a trial which requires registration in ClinicalTrials.gov. The signature on the application of the Authorized Organizational Representative assures compliance for the registration of any such trial.

## 4.2 Inclusion of Women and Minorities

Create a section heading entitled "Inclusion of Women and Minorities" and place it immediately following the "Protection of Human Subjects" section. Although no specific page limitation applies to this section of the application, be succinct. The NIH Policy on the Inclusion of Women and Minorities in Clinical Research is described and referenced in [Section 5.6](#).

Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the protection of human subjects.

In this section of the Research Plan, address, at a minimum, the following four points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table. (Instructions for completing this table are provided below in 4.3.) If using existing specimens and/or data without access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion is

inappropriate (item 3 below). Alternatively, describe the women and minority composition of the population base from whom the specimens and/or data will be obtained. Include the Targeted/Planned Enrollment Table in this section.

2. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
3. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group (see examples below).
4. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Examples of acceptable justifications for exclusion of:

A. **One gender:**

1. One gender is excluded from the study because:
  - inclusion of these individuals would be inappropriate with respect to their health;
  - the research question addressed is relevant to only one gender;
  - evidence from prior research strongly demonstrates no difference between genders; or
  - sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
2. One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.

B. **Minority groups or subgroups:**

1. Some or all minority groups or subgroups are excluded from the study because:
  - inclusion of these individuals would be inappropriate with respect to their health;
  - the research question addressed is relevant to only one racial or ethnic group;
  - evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
  - a single minority group study is proposed to fill a research gap; or
  - sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
  - the size of the study;
  - the relevant characteristics of the disease, disorder or condition; or

- the feasibility of making a collaboration or consortium or other arrangements to include representation.
3. Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity (e.g., uniquely valuable cohorts, stored specimens or existing datasets are of limited minority representation, very small numbers of subjects are involved, or overriding factors dictate selection of subjects, such as matching of transplant recipients or availability of rare surgical specimens).
  4. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

#### **4.2.1 Additional Instructions and Requirements When NIH-Defined Phase III Clinical Trials Are Proposed**

If the proposed research includes an [NIH-Defined Phase III Clinical Trial](#), the section on Inclusion of Women and Minorities also must address whether clinically important sex/gender and/or race/ethnicity differences are expected from the intervention effect. The discussion may include supporting evidence and/or data derived from animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies. The discussion of expected sex/gender and/or race/ethnicity differences in intervention effect must include selection and discussion of one of the following analysis plans:

- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, *or*
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender and racial/ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), *or*
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

#### **4.3 Instructions for Completing the Targeted/Planned Enrollment Tables for Reporting Race and Ethnicity Data for Subjects in Clinical Research**

The NIH Policy on Reporting Race and Ethnicity Data for Subjects in Clinical Research is described and referenced in [Section 5.8](#).

##### **A. New Applications**

All new clinical research studies should collect and report information on participants with respect to two categories of ethnicity and five categories of race. The Inclusion Enrollment Report (<http://grants.nih.gov/grants/funding/phs398/phs398.html>) for reporting summary data on participants to NIH includes two categories of ethnicity and five categories of race and is based on the Office of Management and Budget (OMB) reporting standards for data on race and ethnicity. Investigators should review the instructions and Frequently Asked Questions about using the Enrollment Table format at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>.

When reporting these data in the aggregate, investigators should report: (a) the number of research participants in each ethnic category; (b) the number of research participants who selected only one category for each of the five racial categories; (c) the total number of research participants who selected multiple racial categories reported as the “number selecting more than one race,” and (d) the number of research participants 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 data should be compiled in a way that they can be reported using the required categories.

### **Instructions for Completing Targeted/Planned Enrollment Table**

Provide the study title.

The “Total Planned Enrollment” means the number of subjects that are expected to be enrolled in the study, consistent with the definition in ClinicalTrials.gov.

The “Total Planned Enrollment” will be reported in two ways in the table: by “Ethnic Category” and by “Racial Categories.”

“Ethnic Category”: Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender in the top part of the table.

“Racial Categories”: Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender, in the bottom part of the table. Note that Hispanic is an ethnic, not a racial, category.

If there is more than one study/protocol, provide a separate table for each.

List any proposed racial/ethnic subpopulations below the table.

### **Submitting Applications or Proposals Using Existing Data in Clinical Research with No Plans for Collecting New/Additional Data:**

Investigators are instructed to provide plans for the total number of subjects proposed for the study and to provide the distribution by ethnic/racial categories and sex/gender using the Targeted/Planned Enrollment Table. Under these circumstances, investigators are not required to re-contact subjects solely to comply with the newly revised categories.

### **If Data Collection is Ongoing, Such that New Human Subjects Will be Enrolled and/or Additional Data Will be Collected from Human Subjects:**

Investigators should report ethnicity/race and sex/gender sample composition using the Inclusion Enrollment Report.

### **If Data Collection is Complete, Such that No New/Additional Subject Contact is Planned:**

Investigators should use the Inclusion Enrollment Report.

### **Research Conducted at Foreign Sites:**

If proposed studies involve a foreign site, investigators are encouraged to design culturally sensitive and appropriate data collection instruments that allow research participants to self-identify their racial and ethnic affiliation. However, these items should be designed in a way that they can be aggregated into the OMB-required categories. Also, the investigator can report on any racial/ethnic subpopulations by listing this information in an attachment to the required table. This may be particularly useful when distinctive subpopulations are relevant to the scientific hypotheses being studied.

When completing the tables that describe research in foreign sites, investigators should asterisk and footnote the table indicating that data includes research participants in foreign sites. If the aggregated data only includes participants in foreign research sites, the investigator should provide information in one table with an asterisk and footnote. However, if the study includes both domestic and foreign

sites, the investigator should complete two separate tables – one for domestic and another for foreign participants.

### **B. Renewal Application and Progress Reports**

The Inclusion Enrollment Report (<http://grants.nih.gov/grants/funding/phs398/phs398.html>) must be used for reporting accrual data to the NIH. For Revision applications, any proposed additions to the Targeted/Planned Enrollment Table should be provided, in addition to the Inclusion Enrollment Report. In annual progress reports, investigators conducting clinical research are required to provide the cumulative total enrollment of subjects to-date, showing the distribution by ethnic/racial categories and sex/gender on the Inclusion Enrollment Report, and update the Targeted/Planned Enrollment Table as needed.

## **4.4 Inclusion of Children**

The NIH Policy on Inclusion of Children is referenced and described in [Section 5.7](#). Instructions for item 11 of the Research Plan are as follows:

- Create a section entitled “Inclusion of Children” and place it immediately following the Targeted/Planned Enrollment Table.
- For the purpose of implementing these guidelines, a *child* is defined as an individual under the age of 21 years (for additional information see <http://grants.nih.gov/grants/funding/children/children.htm> and <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>).
- Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, application, or proposal, present an acceptable justification for the exclusion (see below).
- If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
- Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the age-appropriate inclusion or exclusion of children in the research project.
- When children are involved in research, the Additional Protections for Children Involved as Subjects in Research ([45 CFR Part 46 Subpart D](#)) apply and must be addressed under the Protections Against Risk subheading (4.1.2.b).

### **Justifications for Exclusion of Children**

For the purposes of this policy, all individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is not relevant to children.
2. There are laws or regulations barring the inclusion of children in the research.
3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant.  
Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.

4. A separate, age-specific study in children is warranted and preferable. Examples include:
  - a. The condition is relatively rare in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
  - b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
  - c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions planned, to allow inclusion of children rather than excluding them.
5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). Although children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
6. Study designs are aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).
7. Other special cases can be justified by the investigator and found acceptable to the review group and the Institute Director.

## 5. Human Subjects Research Policy

Human Subjects Research Policy includes DHHS regulations for the protection of human subjects and the following NIH policies related to human subjects research.

### 5.1 Protection of Human Subjects

The Department of Health and Human Services (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 the awardee 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 nonexempt research hold a Federal-wide Assurance (FWA) with the Office for Human Research Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects. These regulations, [45 CFR Part 46](#), Protection of Human Subjects, are available from OHRP, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD; telephone: 1-866-447-4777 (toll-free) or (240) 453-6900; email: [ohrp@osophs.dhhs.gov](mailto:ohrp@osophs.dhhs.gov).

Nonexempt research involving human subjects may only be conducted under a DHHS award if the organization is operating in accord with an approved FWA and provides verification that an Institutional Review Board (IRB) that is registered under the specific FWA has reviewed and approved the proposed activity in accordance with the DHHS regulations. No award to an individual will be made unless that individual 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 unless a determination of equivalent protections is made in accord with 45 CFR 46.101(h).

Under DHHS regulations to protect human subjects, certain research areas are [exempt](#). However, if an applicant makes inappropriate designations of the noninvolvement of human subjects or of exempt categories of research, this may result in delays in the review of an application or the return of the application without review. The PHS 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. With the exception of research projects that meet the criteria for Exemption 4, studies that are exempt from the human subjects regulatory requirements must still address the inclusion of women, minorities and children in the study design.

Regulations of the Food and Drug Administration (21 CFR 50, 21 CFR 56) generally apply to biomedical research involving an unapproved drug, device or biologic and may apply to certain studies of approved products. Additional information on FDA regulations is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>. If work falls under FDA's regulatory requirements, the grantee must follow both DHHS and FDA human subject protection regulations.

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. See Part III, 2.9. Research Involving Recombinant DNA, including Human Gene Transfer Research.

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. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable is considered “research involving human subjects.” The NIH Office of Extramural Research Human Subjects website contains additional information and Frequently Asked Questions to help investigators understand how these federal requirements apply to their research. See <http://grants.nih.gov/grants/policy/hs/index.htm>.

The DHHS regulations require the NIH to evaluate all applications and proposals involving human subjects (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.120>). This independent evaluation is conducted at the NIH through the peer review system and NIH staff review, and, as required, will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. On the basis of this evaluation, the NIH may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

## 5.2 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. The subparts describe the additional protections required for conducting research involving these populations. Relevant information may be obtained at the OHRP website (<http://www.hhs.gov/ohrp/policy/index.html>).

REMINDER: DHHS 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](#) 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 educational testing or observations of public behavior when the investigator(s) do not participate in the activities being observed.

### 5.3 Data and Safety Monitoring Plans for Clinical Trials

For each proposed clinical trial, NIH requires a data and safety monitoring plan that describes oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. Prior to the accrual of human subjects, a detailed data and safety monitoring plan must be submitted to the applicant's IRB and to the funding entity for approval. Adverse Events must be reported to the IRB, the NIH funding Institute or Center, and other appropriate offices or agencies. This policy requirement is in addition to any monitoring requirements imposed by [45 CFR Part 46](#). NIH policy specifically requires the establishment of a Data and Safety Monitoring Board (DSMB) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. See also Part III, 2.1 Human Subjects Research.

### 5.4 IRB Approval

NIH does not require certification of IRB approval of the proposed research prior to NIH peer review of an application. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html>.

Following NIH peer review, applicants and their institutions will be notified of the need for review and approval of the proposed research by an IRB that is registered with OHRP. See <http://www.hhs.gov/ohrp/> to register an IRB. Certification of IRB approval must be sent to the Grants Management Office identified in the notice requesting documentation. Certification of IRB review and approval must include: the PHS application number, title of the project, name of the program director /principal investigator, date of IRB approval, and appropriate signatures. Grantees may also use the optional form "Protection of Human Subjects - Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)" (OMB Form No. 0990-0263 <http://www.hhs.gov/ohrp/humansubjects/assurance/OF310.rtf>) to meet this requirement.

The OHRP has determined that an institution is automatically considered to be engaged in human subjects research when it receives an NIH award to support nonexempt human subjects research. See <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>. All institutions engaged in human subjects research must obtain a Federal Wide Assurance (FWA) from OHRP. Instructions for applying for a Federal Wide Assurance (FWA) are available from the OHRP website at [http://www.hhs.gov/ohrp/assurances/assurances\\_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html).

HHS human subject regulations at 45CFR46.101(f) require that each application for non-exempt HHS-supported human subject research be reviewed and approved by an IRB (see also <http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm>). Only the date of approval of the application should be submitted to NIH. However, the IRB must ensure that any corresponding protocol(s) are consistent with the application, and must maintain documentation of IRB approval of all corresponding protocols, including those reviewed by consortium participants.

Any modifications to the Research Plan in the application, required by either NIH or by the IRB, must be submitted with follow-up certification of IRB approval to the NIH before the competing award is made. It is the responsibility of the PD/PI and the applicant organization to submit the follow-up documentation.

If more than a year will have elapsed between the initial IRB review date and the anticipated award date, the awarding unit staff shall require re-review by the IRB prior to award.



## 5.5 Required Education in the Protection of Human Research Participants

NIH requires education on the protection of human research participants for all individuals identified in PHS applications as Senior/key Personnel who will be involved in the design or conduct of human subjects research, 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 at: [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 Senior/key Personnel involved in the design or conduct of human subjects research. Although NIH does not endorse specific programs, there are curricula available that can provide guidance or that can be modified to provide training in this area. See

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp> 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>.

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

NIH policy requires 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 IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the 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).

## 5.7 NIH Policy on Inclusion of Children

Research involving children (see definition of "[child](#)") must comply with the NIH Policy and Guidelines on the Inclusion of Children in Clinical Research. Investigators should obtain full copies of the Policy and Guidelines from NIH staff, or from <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.

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.

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.

## 5.8 NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research

The Office of Management and Budget (OMB) (<http://www.whitehouse.gov/omb/fedreg/ombdir15.html>) defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting agencies (including NIH). The standards were revised in 1997 and 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). Reports of data on race and ethnicity shall use these categories. The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. The following definitions apply to the minimum standards for the ethnic and racial categories.

### 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 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 affiliation 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.

**Ethnic/Racial Subpopulations:** In addition to OMB ethnic and racial categories, NIH uses the following definition for ethnic/racial subpopulations:

Subpopulations: Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study.

## Guidance on Collecting Race and Ethnicity Data from Human Subjects

When an investigator is planning to collect data on ethnicity and race, the categories identified above should be used. The collection of greater detail is encouraged, for example on ethnic/racial subpopulations. However, any collection that uses more detail must be designed in a way that data can be aggregated into these minimally required categories. Use self-report or self-identification to collect this information by asking two separate questions – one on ethnicity and one on race. Collect ethnicity information first followed by the question on race and provide subjects with the option to select more than one racial category. An example of a format for collecting information from study subjects in the US that meets the OMB requirements can be found in the Ethnic Origin and Race section of the Personal Data Form Page <http://grants.nih.gov/grants/funding/phs398/phs398.html> in the PHS 398.

See NIH Policy on [Inclusion of Women and Minorities](#) and [http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm).

## 5.9 Research on Transplantation of Human Fetal Tissue

In signing the application Face Page, the Authorized Organizational 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.

## 5.10 Research Using Human Embryonic Stem Cells

In signing the application Face Page, the Authorized Organizational 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>). See <http://stemcells.nih.gov/index.asp> for additional information on stem cells, and <http://stemcells.nih.gov/policy/guidelines.asp> for Federal policy statements and guidelines on federally funded stem cell research.

## 5.11 ClinicalTrials.gov Requirements

In signing the application Face Page, the Authorized Organizational Representative of the applicant organization certifies that if the research is an applicable clinical trial under Public Law 110-85, the applicant organization will be in compliance with the registration and reporting requirements of Public Law 110-85 (see Part III, [Section 2.1.6](#)).

## **PART III**

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

# 1. Policy

## 1.1 Applications That Include Consortium/Contractual Facilities and Administrative Costs

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

NIH policy provides for exclusion of consortium/contractual F&A when determining if an applicant is in compliance with a direct cost limitation. This policy extends 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). (See also [Notice OD-04-040](#).)

This policy applies to all solicited and investigator-initiated applications and 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 is used for applications requesting \$250,000 or less in direct costs per year. Consortium/contractual F&A costs are not factored into this direct cost limit, however, they may be requested in addition to the \$250,000.

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

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.

## 1.2 Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code

See <http://grants.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 **activity code** and subsequently resubmitted using a different **activity code** (for example, an application that was originally an R01 and is resubmitted as an R21).

Since an RFA often has special considerations of eligibility, scientific scope, and review criteria, unfunded **RFA applications must** be resubmitted as **new** applications to **another FOA**. Similarly, a

change of **activity code** (e.g., from an R01 to an R21, or from an R03 to an R01) 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 **one resubmission** (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>). Do **not** include an Introduction describing the changes and improvements made and do **not** mark text 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 **one resubmission** of the 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 **activity code**. 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 provision for a **resubmission** is clearly delineated in the RFA. In addition, if a subsequent RFA specifically solicits **resubmissions** of unfunded applications from a previous RFA, the instructions in the second RFA should be followed. In all other cases, an application submitted in response to an RFA and then resubmitted as an investigator-initiated application must be **prepared** as a **new** application.
2. When a previously unfunded application **that was** 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.

### 1.3 NIH Policy on Resubmission Applications

See: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html>.

For all original new (i.e., never submitted) and competing renewal applications submitted for the January 25, 2009 due date and beyond, NIH will accept only a single amendment (A1) to the application (called a "resubmission" application). There is no time limit for the resubmission application. Any second resubmission will be administratively withdrawn and not accepted for review. For original new and competing renewal applications submitted prior to January 25, 2009, applicants are permitted two resubmissions (A1 and A2). For these "grandfathered" applications, any second resubmission (A2) must be submitted no later than January 7, 2011, and NIH will not accept any A2 resubmissions after that date. This resubmission policy applies to all NIH extramural applications.

See [NOT-OD-07-083](#) for special conditions and due dates for new investigator resubmission applications submitted for consecutive review cycles. Note this applies only to new investigator R01s submitted for standard receipt dates and reviewed in recurring study sections in CSR.

Although there is no time limit for the A1 resubmission, 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. PD/PIs and their institutions need to exercise their best judgment in determining the advisability of a Resubmission application after several years have elapsed.

The policy limiting the number of Resubmissions was established following analysis of data indicating that investigators who receive initial funding for a resubmitted application have a lower success rate in obtaining support for a subsequent Renewal application. The likelihood of subsequent success decreased with an increasing number of Resubmissions.

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 Resubmission 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.

## **1.4 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 that for the purposes of determining whether this policy applies, this \$500,000 limit excludes any consortium F&A costs.

See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

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 excludes any consortium F&A costs (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-040.html>). 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 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 PD/PI 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.

## 1.5 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been published or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh Dole Act. See the NIH Grants Policy Statement, and the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page: <http://inventions.nih.gov>.

The adequacy of resource sharing plans are considered by reviewers when a competing application is evaluated. Reviewers are asked to describe their assessment of the sharing plan in an administrative note, and will not normally include their assessment in the overall priority score. Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

### 1.5.1 Data Sharing Policy

All investigator-initiated applications with direct costs of \$500,000 or greater in any single year are expected to address data-sharing in their application. Applicants are encouraged to discuss data-sharing plans 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 \$500,000 or greater 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, other Funding Opportunity Announcements (FOAs) may request data-sharing plans for applications that are less than \$500,000 direct costs in any single year.

NIH recognizes that in some cases data-sharing may be complicated or limited by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the HIPAA Privacy Rule. The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would



permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

For more information on data-sharing, please see: [http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/) and the [NIH Final Policy on Sharing Research Data](#).

### 1.5.2 Sharing Model Organism Policy

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

This expectation is for **all** applications where the development of model organisms is anticipated, regardless of funding amount.

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>.

### 1.5.3 Policy for Genome-Wide Association Studies (GWAS)

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition.

All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, [NIH Guide NOT-OD-07-088](#). For additional information see: <http://grants.nih.gov/grants/gwas/>.

## 1.6 Inventions and Patents

NIH Grants Policy and Federal law require NIH recipient organizations to promptly report all inventions that are either conceived or first actually reduced to practice using NIH funding. Invention reporting compliance is described at <http://www.iedison.gov>. Grantees are encouraged to submit reports electronically using Interagency Edison (<http://www.iedison.gov>). 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 37 CFR Section 401.14 is a violation of 35 U.S.C. 202 and may result in loss of the rights of the recipient organization. Inquiries or correspondence should be directed to **Division of Extramural Inventions and Technology Resources, Office of Policy for Extramural Research Administration, OER, NIH, 6705 Rockledge Dr., Suite 310, MSC 7980, Bethesda, MD 20892-7980, Telephone: (301) 435-1986.**

## 1.7 Just-In-Time Policy

Several elements of an application are not required at the time the application is submitted. Instead, this information is requested later in the review cycle (i.e., “just-in-time”) to minimize burden to institutions and to ensure that the information is current. The information eligible for just-in-time submission includes:

- **Current Other Support:** See 1.8 Other Support policy information below. Use the sample format provided on the Other Support Format Page (MS WORD or PDF). For all Senior/key Personnel, provide details on adjustment of any budgetary, scientific, or effort overlap if the application is funded.  
  
For Career Development Award applicants, information on all active support for the candidate, mentor(s), co-mentor(s), and Senior/key Personnel may be requested by the awarding component prior to award.
- **Certifications:**
  - If research involving human subjects is proposed, the Federal-wide Assurance number (if not previously provided) and the Certification of IRB Review and Approval of the research proposed in the application. Pending or out-of-date approvals cannot be accepted. See [Part II.5.4 IRB Approval](#).
  - If research involving live vertebrate animals is proposed, Animal Welfare Assurance number of the applicant organization, date of IACUC approval of the research proposed in the application, and any IACUC-imposed changes. Pending or out-of-date approvals cannot be accepted. IACUC approval must be dated within the last three years to be valid.
- **Human Subjects Education:** For applications that propose human subjects research, certification that each person identified as Senior/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 Part II, 5.5.
- 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 just-in-time information 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 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>.

## 1.8 Other Support

Do not submit information on Other Support with the application beyond that required in the biographical sketch. See 1.7 Just-in-Time Policy.

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.

Do not confuse Research Support with Other Support. Though they sound similar, these parts of the application are distinctly different. As part of the biosketch section of the application, Research

Support highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualification of the research team. In contrast, Other Support information is required for all applications that are selected to receive grant awards and includes detailed financial information. NIH staff will request complete and up-to-date "other support" information *after* peer review. This information will be used to check that the proposed research is not already funded through other sources.

## 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 (i.e., 12 person months), 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 (i.e., 12 person months), whether or not salary support is requested in the application. While information on other support is only requested for Senior/key Personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent or 12 person months.

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 PD/PI, and awarding agency staff.

## 1.9 Graduate Student Compensation

The maximum amount NIH will award 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). 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.

## 1.10 DUNS Number

Applicant organizations **must** have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. See instructions in Part I, Section 4.1, [item 11](#).

## 1.11 Public Access Policy

The Public Access Policy ensures that the public has access to the published results of NIH funded research at the NIH National Library of Medicine's (NLM) PubMed Central (PCM), a free digital archive of full-text biomedical and life sciences journal literature [<http://www.pubmedcentral.nih.gov/>]. Under the Policy NIH-funded investigators are required by Federal law to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication on or after 4/7/2008, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy. Applicants citing articles in NIH applications, proposals,

and progress reports that fall under the Policy, were authored or co-authored by the applicant and arose from NIH support must include the PubMed Central reference number (PCMID) or NIH Manuscript Submission reference number (NIHMS ID).

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

Additional information can be found at: <http://publicaccess.nih.gov/>.

## 1.12 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.

## 1.13 Transition to the SF424 (R&R) Application and Electronic Submission through Grants.gov

As first announced in August 2005 ([NOT-OD-05-067](#)), NIH is transitioning from the PHS 398 application to the SF424 (R&R) application and electronic submission through Grants.gov. This transition is being done by grant mechanism. Applicants should refer to the Timeline to determine when a particular mechanism has transitioned to the new form and electronic submission. Information on Transition Strategy and Timeline can be found at: [http://era.nih.gov/ElectronicReceipt/strategy\\_timeline.htm](http://era.nih.gov/ElectronicReceipt/strategy_timeline.htm).

For more information on NIH's transition plans, see the website for Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>.

## 2. 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 the project, program, or type of applicant organization. There are a number of additional public policy requirements with which applicants and grantees must comply. Contact the 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 Authorized Organizational Representative of the applicant organization certifies that the applicant organization will comply with the following policies, assurances and/or certifications:

[Human Subjects Research](#)

[Research on Transplantation of Human Fetal Tissue](#)

[Research Using Human Embryonic Stem Cells](#)

[Women and Minority Inclusion Policy](#)

[Inclusion of Children Policy](#)

[ClinicalTrials.gov Requirements](#)

[Vertebrate Animals](#)

[Debarment and Suspension](#)

[Drug-Free Workplace](#)

[Lobbying](#)

[Non-Delinquency on Federal Debt](#)

[Research Misconduct](#)

[Civil Rights](#)

[Handicapped Individuals](#)

[Sex Discrimination](#)

[Age Discrimination](#)

[Recombinant DNA, including Human Gene Transfer Research](#)

[Financial Conflict of Interest](#)

[Smoke-Free Workplace](#)

[Prohibited Research](#)

[Select Agent Research](#)

[Program Director/Principal Investigator\(s\) Assurance](#)

[Impact of Grant Activities on the Environment and Historic Properties](#)

## 2.1 Human Subjects Research

(See also [Part II: Supplemental Instructions for Preparing the Protection of 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 the awardee 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 hold a Federal-wide Assurance (FWA) with the [Office for Human Research Protections \(OHRP\)](#), and establish 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 20852; telephone: 1-866-447-4777 (toll-free) or (240) 453-6900; email: [ohrp@osophs.dhhs.gov](mailto:ohrp@osophs.dhhs.gov).

Non-exempt research involving human subjects may only be conducted under a DHHS award if the organization is operating in accord with an approved FWA and provides verification that an Institutional Review Board (IRB) that is registered under the specific FWA has reviewed and approved the proposed activity in accordance with the DHHS regulations. No award to an individual will be

made unless that individual 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 unless a determination of equivalent protections is made in accord with 45 CFR 46.101(h).

Under DHHS regulations to protect human subjects, certain research areas are exempt. (See [Exemption Categories](#)). With the exception of research projects that meet the criteria for Exemption 4, studies that are exempt from the human subjects regulatory requirements must still address the inclusion of women, minorities and children in the study design.

Regulations of the Food and Drug Administration (21 CFR 50; 21 CFR 56) generally apply to biomedical research involving an unapproved drug, device or biologic, and may apply to certain studies of approved products. Additional information on FDA regulations is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>. If work falls under FDA's regulatory requirements, the grantee must follow both DHHS and FDA human subject protection regulations.

## 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. The subparts describe the additional protections required for conducting research involving these populations. Relevant information may be obtained at the OHRP website (<http://www.hhs.gov/ohrp/policy/index.html>).

REMINDER: DHHS 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 Exemptions under Human Subjects Research Definitions and Terms, Part III.3) 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 educational testing or observations of public behavior when the investigator(s) do not participate in the activities being observed.

## Data and Safety Monitoring

For each proposed clinical trial, NIH requires a data and safety monitoring plan that describes oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. Prior to the accrual of human subjects, a detailed data and safety monitoring plan must be submitted to the applicant's IRB and to the funding entity for approval. Adverse Events must be reported to the IRB, the NIH funding Institute or Center, and other appropriate offices or agencies. This policy requirement is in addition to any monitoring requirements imposed by [45 CFR Part 46](#).

NIH Policy specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. A DSMB also may be appropriate for clinical trials if the studies are blinded (masked), employ high-risk interventions, or involve vulnerable populations.

Summary reports of adverse events must be provided to the NIH funding IC and 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 in PHS applications as Senior/key Personnel who will be involved in the design or conduct of human subjects research, 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 at [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 Senior/key Personnel involved in the design or conduct of human subjects research. Although NIH does not endorse specific programs, there are curricula available that can provide guidance or that can be modified to provide training in this area. See

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp> 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>.

### 2.1.1 Research on Transplantation of Human Fetal Tissue

In signing the application Face Page, the Authorized Organizational 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.

### 2.1.2 Research Using Human Embryonic Stem Cells

In signing the application Face Page, the Authorized Organizational 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>). See also <http://stemcells.nih.gov/index.asp> for additional guidance on stem cells and <http://stemcells.nih.gov/policy/guidelines.asp> for Federal policy statements and guidelines on federally funded stem cell research.

### 2.1.3 NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research

NIH policy requires 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 IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the 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).

#### **2.1.4 NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research**

See NIH Policy on Reporting Ethnicity/Race and Sex/Gender in Clinical Research in [Part II, 5.8](#).

The Office of Management and Budget (OMB) defines 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 standards were revised in 1997 and 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. 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.

Collection of this information and use of these categories is required for research that meets the NIH definition of [clinical research](#). See Part II, 5.8 for additional information.

#### **2.1.5 NIH Policy on Inclusion of Children**

Research involving children (see definition of “[child](#)”) must comply with the NIH Policy and Guidelines on the Inclusion of Children in Clinical Research. Investigators should obtain full copies of the Policy and Guidelines from NIH staff, or from <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.

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.

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.

#### **2.1.6 ClinicalTrials.gov**

In signing the application Face Page, the Authorized Organizational Representative of the applicant organization assures compliance with Public Law 110-85, enacted 09/27/2007, if applicable ([http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ085.110.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf)). The law amends the Public Health Service Act to expand the scope of clinical trials that must be registered in ClinicalTrials.gov. It also increases the number of registration fields that must be submitted, requires certain results information to be included, and sets penalties for noncompliance.

The trials that must be registered are called “applicable clinical trials.” Under the statute these trials generally include: (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. NIH encourages registration of ALL trials whether required under the law or not.

For additional information see NIH Guide Notices at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html>.

## 2.2 Vertebrate Animals

The *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) mandates that an approved Animal Welfare Assurance must be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all grantee organizations receiving PHS support to conduct research using live vertebrate animals. The PHS Policy requires grantee organizations to establish appropriate policies and procedures to ensure the humane care and use of animals. The PHS policy stipulates that the grantee organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS supported research activities. This policy incorporates the *U.S.*

*Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* and requires that institutions base their animal care and use programs on the *Guide for the Care and Use of Laboratory Animals*. This policy does not supersede 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 with the applicable regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act 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 (<http://grants.nih.gov/grants/olaw/olaw.htm>).

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 including custom antibody preparation.

In addition to an approved Animal Welfare Assurance, the grantee organization must provide verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity. IACUC approval must be dated within the last three years in order to be valid. IACUCs are not authorized to administratively extend approval beyond three years. Verification of IACUC approval is requested under Just-in-Time policy (prior to award) (see [1.7](#)). Foreign grantees receiving direct support are not required to provide IACUC approval, but must have an approved Assurance.

Under consortium (subaward) agreements in which the grantee collaborates with one or more other organizations, the grantee, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the grantee as specified in the NIHGPS (See NIH GPS, Part II, Terms and Conditions of NIH Grant Awards, Consortium Agreements). The animal welfare requirements that apply to grantees also apply to consortium participants and subprojects. The prime grantee is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has a valid IACUC approval.

If the prime grantee does not have an Animal Welfare Assurance and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an Inter-institutional Assurance from OLAW. When the grantee is a domestic institution and there is a foreign Project/Performance Site using animals, the grantee must ensure that the Project/Performance Site has an approved Assurance and must provide verification of IACUC approval by the domestic grantee's IACUC. This is

to certify to NIH that the activity as conducted at the foreign Project/Performance Site is acceptable to the grantee organization. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals must comply with the Council for International Organizations of Medical Sciences' *International Guiding Principles for Biomedical Research Involving Laboratory Animals* ([http://www.cioms.ch/frame\\_1985\\_texts\\_of\\_guidelines.htm](http://www.cioms.ch/frame_1985_texts_of_guidelines.htm)) and all laws, regulations and policies governing the care and use of laboratory animals in the jurisdiction in which the research will be conducted.

## 2.3 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 2 CFR 180 and 376, "Government-wide Debarment and Suspension (Nonprocurement)." Changes in this Government-wide requirement implement this as a term and condition of an award.

## 2.4 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.

## 2.5 Lobbying

a) 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.

b) 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.

## 2.6 Non-Delinquency 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.

## 2.7 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 42 CFR Part 93, "Public Health Service Policies on Research Misconduct."

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 research misconduct under 42 CFR Part 93;
2. The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 93;
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.

Research Misconduct is defined by the Public Health Service as “fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”

- (a) Fabrication is making up data or results and recording or reporting them.
- (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- (c) Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.
- (d) Research misconduct does not include honest error or differences of opinion.

For further information, please contact:

U.S. Dept of Health and Human Services  
Office of Research Integrity  
1101 Wootton Parkway, Suite 750  
Rockville, MD 20852  
AskORI@osophs.hhs.gov  
Phone: (240) 453-8200  
Fax: (301) 443-5351.

## **2.8 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 DHHS 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 DHHS 690 is available from <http://www.hhs.gov/ocr/ps690.pdf>.

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

## **2.9 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*. More information about the NIH Guidelines and IBCs can be found at: <http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm>. Further, the *NIH Guidelines*, in Appendix M, include special review and reporting requirements for the conduct of human gene transfer studies. 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 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838. Additional information on the special requirements that pertain to human gene transfer can be found in a series of Frequently Asked Questions at: [http://www4.od.nih.gov/oba/RAC/RAC\\_FAQs.htm](http://www4.od.nih.gov/oba/RAC/RAC_FAQs.htm).

## 2.10 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 within 60 days of identification.
4. When the Institution determines that a financial conflict of interest exists (see #2 and #3 above), the institution must notify the NIH awarding component Chief Grants Management Officer of its existence and provide the following information:
  - Grant number and Principal Investigator;
  - Name of Investigator with FCOI; and
  - Distinguish which method was used to protect the involved PHS funded research from bias (i.e., managed, reduced, or eliminated).
5. When requested, the institution will make information available to NIH regarding all identified conflicting interests and how those interests have been managed, reduced, or eliminated to protect the research from bias.

## 2.11 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.

## 2.12 Prohibited Research

NIH Appropriation Acts have limited the use of NIH funding for a number of years and typically continue the same limitations from year to year. These legislative mandates appear in the Public Law 110-005 that authorizes NIH appropriations:

### **BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

NIH is prohibited 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 at <http://stemcells.nih.gov/index.asp>.

### **LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES**

"(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**

"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**

"(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."

## 2.13 Select Agent Research

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/pdfs/42\\_cfr\\_73\\_final\\_rule.pdf](http://www.cdc.gov/od/sap/pdfs/42_cfr_73_final_rule.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.

In addition to the above requirements, research involving **both select agents and recombinant DNA** is also subject to the NIH Guidelines for Research Involving DNA Molecules (NIH Guidelines) (see [Section 2.9 Research Involving Recombinant DNA, including Human Gene Transfer Research](#) in this subsection for applicability of these guidelines).

For additional information regarding Select Agent research, see the following websites maintained by NIH, CDC, and USDA:

NIH Office of Extramural Research Select Agent Information:  
[http://grants.nih.gov/grants/policy/select\\_agent/](http://grants.nih.gov/grants/policy/select_agent/)

Center for Disease Control Select Agent Program:  
<http://www.cdc.gov/od/sap/index.htm>

Center for Disease Control Select Agent Program Guidelines:  
<http://www.cdc.gov/od/sap/guidelines.htm>

Center for Disease Control Select Agent Program Public Laws and Regulations:  
<http://www.cdc.gov/od/sap/regulations.htm>

Center for Disease Control Select Agent Program Related Links:  
<http://www.cdc.gov/od/sap/regulations.htm>

Animal and Plant Health Inspection Service (APHIS) Select Agent Program:  
[http://www.aphis.usda.gov/programs/ag\\_selectagent/](http://www.aphis.usda.gov/programs/ag_selectagent/)

## 2.14 Program Director/Principal Investigator Assurance

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

## 2.15 Impact of Grant Activities on the Environment and Historic Properties

All NIH grants, whether or not they include construction or major alteration and renovation activities, are subject to the requirements of the National Environmental Policy Act of 1969 (ACT), as amended. This Act requires Federal agencies to consider the probable environmental consequences of all grant-supported activities. As part of NIH's implementation of this Act, grantees are required to promptly notify NIH of any probable impacts on the environment from grant-supported activities, or certify that no such activities exist upon receipt of a grant award. This requirement is in addition to the other public policy requirements for grants for construction and alteration and renovation activities



discussed more fully in the NIH Grants Policy Statement Construction Grants – Public Policy Requirements and Objectives.

Additionally, all NIH grant awards should not involve activities that violate provisions of the National Historic Preservation Act of 1966 or other statutory requirements. All grantees are subject to the requirements of Executive Order 13287 – Preserve America, requiring notification to NIH of all activities that would affect any historic property, or certification that no impact will occur upon receipt of the grant award or in a post-award action without NIH prior approval. For the purposes of the Order, historic property is defined to include any prehistoric or historic district, site, or object included in, or eligible for inclusion in, the National Register of Historic Places maintained by the Secretary of the Interior. This term includes artifacts, records, and remains that are related to and located within such properties. The term includes properties of traditional religious and cultural importance to an Indian tribe or Native Hawaiian organization and that meet the National Register criteria.

### 3. 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, any collaborating site, or other Project/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 and controlled by either: (a) one or more natural persons (individuals who are citizens of, or permanent resident aliens in, the United States); or (b) another for-profit business concern that is itself at least 51% owned and controlled by one or more natural persons (individuals who are citizens of, or permanent resident aliens in, the United States)(See 13 CFR 121.105 (defining “business concern”)).
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 Part 121, as is the process for calculating “number of employees.”

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.

**Clinical Trial.** See [Human Subjects Research Definitions and Terms](#).

**Coded.** See [Human Subjects Research Definitions and Terms](#)

**Co-investigator.** An individual involved with the PD/PI 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 Senior/key Personnel. The designation of a co-investigator, if applicable, does not affect the PD/PI's roles and responsibilities as specified in the [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 PD/PI 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 instrument that will have substantial Federal scientific and/or programmatic involvement. Substantial 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 \$5,000 or the capitalization threshold established by the organization, whichever is less.

**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.

#### **Human Subjects Research Definitions and Terms.**

**Autopsy Materials.** The use of autopsy materials is governed by applicable federal, state and local law and is not directly regulated by 45 CFR Part 46.

**Child.** The NIH Policy on Inclusion of Children defines a child as an individual under the age of 21 years. The intent of the NIH policy is to provide the opportunity for children to participate in research studies when there is a sound scientific rationale for including them, and their participation benefits children and is appropriate under existing Federal guidelines. Thus, children must be included in NIH conducted or supported clinical research unless there are scientific **or** ethical reasons not to include them.

DHHS Regulations ([45 CFR Part 46, Subpart D](#), Sec.401-409) provide additional protections for children involved as subjects in research, based on this definition: "Children are persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted." Generally, state laws define

what constitutes a “child.” Consequently, the age at which a child's own consent is required and sufficient to participate in research will vary according to state law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

**Clinical Research.** NIH defines human clinical research as research with human subjects that is: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

**Clinical Trial.** The NIH defines a *clinical trial* as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.

Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits this definition of a clinical trial.

Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision making for the subject or the test itself imposes more than minimal risk for subjects.

Biomedical clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

**Phase I** clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects).

**Phase II** clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

**Phase III** studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

**Phase IV** studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

**NIH-Defined Phase III Clinical Trial.** An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

**Coded.** With respect to private information or human biological specimens, *coded* means that:

- identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof (i.e., the code); and
- a key to decipher the code exists, enabling linkage of the identifying information with the private information or specimens.

Research that involves only coded private information/data or coded human biological specimens may not constitute human subjects research under the DHHS human subjects regulations (45 CFR 46) if:

- the specimens and/or information/data are not obtained from an interaction/intervention with the subject specifically for the research; and
- the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researcher's access to subject identities is prohibited).

Individuals who provide coded information or specimens for proposed research and who also collaborate on the research involving such information or specimens are considered to be involved in the conduct of human subjects research.

(See the following guidance from the Office for Human Research Protections (OHRP) for additional information and examples:

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.)

**Data and Safety Monitoring Plan.** For each clinical trial, NIH requires a data and safety monitoring plan that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects. The reporting of Adverse Events must be reported to the IRB, the NIH funding Institute or Center, and other required entities. This policy requirement is in addition to any monitoring requirements imposed by [45 CFR Part 46](#).

**Data and Safety Monitoring Board (DSMB).** NIH requires the establishment of a Data and Safety Monitoring Board (DSMB) for multi-site clinical trials involving interventions that entail potential risk to the participants, *and generally for Phase III clinical trials*.

**Exemptions.** The six categories of research exempt from the DHHS human subject regulations are:

**Exemption 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Exemption 2:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:

- (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 2 for research involving survey or interview procedures or observation of public behavior, does not apply to research with children (see [45 CFR Part 46, Subpart D](#)), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

**Exemption 3:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**Exemption 4:** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

The human subjects regulations decision charts (<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>) of the Office of Human Research Protection (OHRP) will determine whether the research falls under the human subjects regulations and if so, whether it meets the criteria for Exemption 4. The NIH Office of Extramural Research website also contains information that is helpful for determining whether human subjects research meets the criteria for Exemption 4. See <http://grants.nih.gov/grants/policy/hs/index.htm>.

Research that meets the criteria for Exemption 4 is not considered "clinical research" as defined by NIH. Therefore the NIH policies for inclusion of women, minorities and children in clinical research, and targeted/planned enrollment tables, do not apply to research projects covered by Exemption 4.

**Exemption 5:** Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads and that are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs (ii) procedures for obtaining benefits or services under those programs (iii) possible changes in or alternatives to those programs or procedures or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

**Exemption 6:** Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**Gender.** Refers to the classification of research subjects into either or both of two categories: women and men. In some cases, representation is unknown because gender composition cannot be accurately determined (e.g., pooled blood samples or stored specimens without gender designation).

**Human Subjects.** The DHHS regulations "Protection of Human Subjects" (45 CFR 46, administered by OHRP) define a **human subject** as a living individual about whom an *investigator* conducting research obtains:

- data through *intervention* or *interaction* with the individual or
- *identifiable private information*.

Italicized words and phrases in the definition of human subjects are defined as follows:

**Investigator.** The OHRP considers the term investigator to include anyone involved in conducting the research. OHRP does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. However, if the individuals who provide *coded* information or specimens also collaborate on other activities related to the conduct of the research with the investigators

who receive such information or specimens, they will be considered to be involved in the conduct of the research. (See OHRP's [2004 Coded Specimen Guidance](#).)

**Research.** DHHS regulations define *research* at 45 CFR 46.102(d) as follows:

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

**Obtains.** In its guidance for use of coded specimens, OHRP has determined that under the definition of human subject at 45 CFR 46.102(f), *obtaining* identifiable private information or identifiable specimens for research purposes constitutes human subjects research. *Obtaining* means receiving or accessing identifiable private information or identifiable specimens for research purposes. OHRP interprets *obtaining* to include an investigator's use, study, or analysis for research purposes of *identifiable private information* or identifiable specimens already in the possession of the investigator.

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102(f))

**Interaction** includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(f))

**Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be *individually identifiable* (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (45 CFR 46.102(f))

**Individually Identifiable Private Information.** According to its guidance for use of coded specimens, OHRP generally considers private information or specimens to be *individually identifiable* as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through *coding* systems. Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

**Significant Difference.** For purposes of NIH policy, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

**Valid Analysis.** This term means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are: allocation of study participants of both sexes/genders (males and females) and from different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization; unbiased evaluation of the outcome(s)



of study participants; and use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the gender and racial/ethnic groups.

**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 paid by an organization for an employee’s appointment, whether that individual’s time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organization 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.

**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 is also be an appropriate designation for mentors on Career awards.

**Person Months.** A metric for expressing the effort (amount of time) that PD/PIs, faculty and other Senior/key Personnel devote to a specific project. Effort is expressed as a percentage of the total institutional appointment and is based on the organization’s regular academic-year, summer or calendar-year.

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

**Program Income.** Gross income earned by the 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; or
- A systematic study directed specifically toward applying new knowledge to meet a recognized need; or
- 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.

**Senior/key Personnel.** The PD/PI and other individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries or compensation is requested under the grant.

Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered if their involvement meets the definition of Senior/key Personnel. Consultants should also be included if they meet the definition of Senior/key Personnel. Senior/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 Senior/key Personnel.

**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).

**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.

## 4. General Information

### 4.1 Research Grant Mechanisms

The following tables summarize the major mechanisms NIH uses to fund research grants. For more detailed information, visit the OER website [http://grants.nih.gov/grants/funding/funding\\_program.htm](http://grants.nih.gov/grants/funding/funding_program.htm).

NIH continues to transition applications from the PHS398 to the SF424 (R&R) and electronic submission through Grants.gov by grant mechanism. Some of the mechanisms described in the chart below have already transitioned; others will transition in the near future. Applicants should refer to the Timeline to determine when a particular mechanism has transitioned to the new form and electronic submission: [http://era.nih.gov/ElectronicReceipt/strategy\\_timeline.htm](http://era.nih.gov/ElectronicReceipt/strategy_timeline.htm).

For more information on NIH's transition plans, see the website for Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>.

#### Research Grants

TYPE (MECHANISM)	DESCRIPTION
<b>Basic Research Grant (R01)</b> <a href="http://grants.nih.gov/grants/funding/r01.htm">http://grants.nih.gov/grants/funding/r01.htm</a>	Basic Research Grants 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>	Small Research Grants 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. Not all awarding components accept investigator-initiated R03 applications.  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="#">Part I, 1.4</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>	Academic Research Enhancement Awards 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.

TYPE (MECHANISM)	DESCRIPTION
<p><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></p>	<p>Exploratory/Developmental Research Grants 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. Not all awarding components accept R21/R33 applications.</p>
<p><b>Small Business Innovation Research Grant (SBIR: R43/R44)</b>  <b>Small Business Technology Transfer Grant (STTR: R41/R42)</b>  <a href="http://grants.nih.gov/grants/funding/sbir.htm">http://grants.nih.gov/grants/funding/sbir.htm</a></p>	<p>SBIR and STTR grants are made to eligible domestic for-profit small business concerns conducting innovative research that has the potential for commercialization. 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>Program Project Grants 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. Not all awarding components accept P01 applications.</p>
<p><b>Research Center Grant (P50/P60)</b></p>	<p>Research Center Grants 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. Not all awarding components accept P50/P60 applications.</p>
<p><b>Scientific Meeting Support (R13)</b>  <a href="http://grants.nih.gov/grants/funding/r13/index.htm">http://grants.nih.gov/grants/funding/r13/index.htm</a></p>	<p>Most NIH ICs provide 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>. Applicants must obtain IC approval prior to submission.</p>

TYPE (MECHANISM)	DESCRIPTION
Research Grants to Foreign Institutions and International Organizations	<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>
Health Services Project Application (5161-1)	Substance Abuse and Mental Health Services Administration (SAMHSA) (301) 436-8451

### Training, Fellowships and Career Development Programs

TYPE (MECHANISM)	DESCRIPTION
<b>Institutional Research Training Including Ruth L. Kirschstein National Research Service Awards (T32/T34/T35)</b> <a href="http://grants.nih.gov/training/nrsa.htm">http://grants.nih.gov/training/nrsa.htm</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 Part I, Section 8 Instructions for Preparing an Institutional Research Training Application.
<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. NRSA APPLICANTS MUST USE PHS 416-1 FORMS/INSTRUCTIONS ( <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 Part I, Section 7 Preparing an Individual CDA Application.

### Applications Available from Other Offices

TYPE (MECHANISM)	DESCRIPTION
International Research Fellowship Award Application (NIH 1541-1)	Fogarty International Center (FIC) (301) 496-1653
Nonresearch Training Grant Application (PHS 6025)	Health Resources and Services Administration (HRSA) (301) 443-6960
Health Services Project Application (5161-1)	Substance Abuse and Mental Health Services Administration (SAMHSA) (301) 436-8451

## 4.2 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 commercial courier deliveries (i.e. FEDEX, UPS, DHL, etc.) 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 NOT 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.

### **4.3 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.

## 4.4 Information Available to the Program Director(s)/Principal Investigator(s)

Under the provisions of the Privacy Act, PD/PIs may request copies of records pertaining to their grant applications from the PHS component responsible for funding decisions. PD/PIs 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.

## 4.5 Information Available to the General Public

PHS makes information about grant awards available to the public, including the title of the project, the grantee institution, the PD/PI, 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 available to the public and used for the dissemination of scientific information and for scientific classification and program analysis purposes. In addition, NIH routinely places information about awarded grants, including project title, name of the PD/PI, 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 grant documents and records when requested by the public, regardless of the intended use of the information. These policies and regulations apply to information in the possession of NIH and generally do not require grantees to permit access to their records except as described in 4.6 Access to Research Data, below. 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 (new, Renewal, and Revision) 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.

## 4.6 Access to Research Data

As required by regulation 45 CFR 74.36, grantees that are institutions of higher education, hospitals, or non-profit organizations must release “research data” first produced in a project supported in whole or in part with Federal funds if they are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). The term “research data” is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

This requirement to release research data does not apply to commercial organizations or to research data produced by state or local governments. However, if a state or local governmental grantee contracts with an educational institution, hospital or non-profit organization, and the contract results in covered research data, those data are subject to these disclosure requirements. See [http://grants.nih.gov/grants/policy/data\\_sharing/index.htm](http://grants.nih.gov/grants/policy/data_sharing/index.htm).