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**U.S. Department of Health and Human Services
Public Health Service**

SF424 (R&R) Individual Fellowship Application Guide for NIH and AHRQ

A guide developed and maintained by NIH for preparing and submitting individual fellowship applications via Grants.gov to NIH and AHRQ using the SF424 (R&R)

Adobe Forms Version B (to be used with FOAs specifying use of Adobe-Forms-B application packages)

February 5, 2010

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PART I

**Instructions for Preparing and Submitting
an Application**

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1. Foreword

This application guide contains instructions and other useful information for preparing Fellowship applications to the National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ) Individual Fellowships.

This application guide is a companion document to a new set of application forms, the SF424 Research and Related (R&R). In addition to the SF424 (R&R) form components, fellowship applications to NIH and AHRQ will include agency-specific components in the “PHS Fellowship Supplemental Form,” as approved and cleared by the PHS 416 (OMB No. 0925-0002). These PHS Fellowship components were developed to continue the collection of agency-specific data required for a complete application. While these agency-specific components are not identical to the PHS 416-1 Fellowship application form pages, the PHS Fellowship reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to NIH and AHRQ will include SF424 (R&R) components and PHS Fellowship components. Instructions for all application components, SF424 (R&R) and “PHS Fellowship Supplemental Form,” are found in this document.

The use of these new forms also involves electronic submission of completed applications through Grants.gov. NIH and AHRQ will gradually transition all activity codes to the new application forms and Grants.gov submission. Specific Funding Opportunity Announcements (FOAs) will clearly indicate which forms and submission process an applicant should use. NIH will continue to use Requests for Applications (RFAs) and Program Announcements (PAs) as categories of FOAs. See [Section 2.4.2](#) for definitions.

Fellowship applicants must carefully review FOAs for guidance on when to use the 424 (R&R) forms, instructions, and electronic submission for a specific activity code, i.e., F05, F30, F31, F32, F33, F37, etc. This process will apply to all types of submissions for the announced activity code—new, resubmission and renewal grant applications. Each FOA will include a link to the most current version of these instructions. Applicants are encouraged to check the Web site frequently for the most current version.

For purposes of this document, any references to “NIH” may also mean “NIH and the Agency for Healthcare Research and Quality (AHRQ).”

1.1 Application Guide Format

This application guide is organized into three distinct parts:

Part I: Instructions for Preparing and Submitting the Application. Part I includes specific instructions for completing the application form components as well as information on electronically submitting applications through Grants.gov.

Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan. Part II is to be used if your proposed research will involve human subjects. These instructions assist you in determining whether human subjects are involved and include six possible scenarios and detailed instructions for completing Items 6-12 of the PHS Fellowship Supplemental Form.

Part III: Policies, Assurance, Definitions, and Other Information. Part III includes information on policies, assurances, definitions, and other information relating to submission of applications to the PHS. Applicants should refer to this document as well as the 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 (including AHRQ) use the [HHS Grants Policy Statement](#).

1.2 NIH and AHRQ Extramural Research and Research Training Programs

The NIH Office of Extramural Research Grants homepage (<http://grants.nih.gov/grants/oeer.htm>) provides an array of helpful information. Applicants are encouraged to bookmark this site and visit it often.

The Division of Communications and Outreach (DCO) is the central source for general information about NIH extramural research and research training programs, funding activity codes, the peer review system, and application procedures. Grants Information (GrantsInfo) is a communication service within the DCO. Information about the NIH extramural research and research training programs, funding opportunities, and the grant application process, can be obtained by emailing your request to: GrantsInfo@nih.gov or by calling (301) 435-0714.

Guidelines for Kirschstein-NRSA Individual Fellowships and non-NRSA may be found on the NIH Web Site at <http://grants.nih.gov/training/nrsa.htm>. Guidelines for the AHRQ fellowships may be found on the AHRQ Web Site at <http://www.ahrq.gov/fund/hhspolicy.htm>.

1.3 Fellowship Activity Codes and Program Guidelines

The Kirschstein-NRSA program helps ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Kirschstein-NRSA fellowships are awarded as a result of national competition for research training in specified health-related areas. Certain specialized individual fellowships, such as the predoctoral fellowships (F31 and F30), postdoctoral fellowships (F32), Senior Fellowships (F33), and other institute-specific fellowship programs are provided under this authority. For individual predoctoral fellowships, NIH Institutes and Centers (ICs) have differing requirements. All NIH ICs except Fogarty International Center (FIC) and National Library of Medicine (NLM) award Kirschstein-NRSA fellowships. FIC and NLM have unique funding authorities for fellowships that are not under the Kirschstein-NRSA authority.

This Application Guide contains information for preparing applications for Individual Fellowships available from the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ). These fellowships are available at the predoctoral, postdoctoral, and senior fellowship levels. These include both Ruth L. Kirschstein National Research Service Award (NRSA) and non-NRSA programs. It is important to note that not all predoctoral, postdoctoral, and senior fellowships are supported by each IC and AHRQ. Therefore, individuals interested in this type of award are strongly encouraged to consult with the appropriate NIH IC and AHRQ before submitting an application. (For example, Postdoctoral (F32) fellowships are provided by the NIH ICs and AHRQ. AHRQ does not provide senior fellowships.) *This action is of utmost importance because applications with marginal or no relevance to the mission of the participating ICs or AHRQ will not be accepted for review or funding.* Thus, specific FOAs always should be consulted for guidance.

Contact information can be found in each Funding Opportunity Announcement (FOA) published as a program announcement or request for applications and below in the [Interactions with NIH and AHRQ Staff section](#).

For more information, see the NIH Research Training and Career Development Web site at <http://grants.nih.gov/training/extramural.htm> and the AHRQ Research Training Web site at <http://www.ahrq.gov/fund/training/rsrchtng.htm>.

A partial list of fellowship activity codes is provided below. As noted in the descriptions in [Part III: Policies, Assurances, Definitions, and Other Information](#), not all awarding components use all activity

codes or programs. For a complete listing of program guidelines, visit the OER Grants Web site http://grants.nih.gov/grants/funding/funding_program.htm.

Kirschstein-NRSA Programs:

- [Individual Ruth L. Kirschstein National Research Service Award Fellowships \(NRSA\) \(F30, F31, F32, F33, F34, etc.\)](#)

Other Individual Fellowship (non-NRSA) Programs:

- [NLM Individual Fellowship for Informationist Training \(F37\)](#)
- [International Neuroscience Fellowship \(F05\)](#)

1.4 Interactions with NIH and AHRQ Staff

Applicants are encouraged to communicate with NIH and AHRQ staff throughout the entire application, review and award process. Web site addresses and phone numbers of relevant NIH awarding components and AHRQ are listed in the table below. A list of contacts specifically for extramural training at the NIH ICs can also be found at http://grants.nih.gov/training/tac_training_contacts.doc. For AHRQ, see <http://www.ahrq.gov/fund/training/trgstaff.htm>. Individuals always are encouraged to check this Web site for the most current contact information.

Table 1.4-1. PHS Agency Contact Table

PHS AGENCY (LINK TO WEB SITE)	AWARDING COMPONENT (LINK TO WEB SITE)	TELEPHONE NUMBER
NATIONAL INSTITUTES OF HEALTH (NIH)	Eunice Kennedy Shriver National Institute of Child Health and Human Development	301-496-0104
NIH	Fogarty International Center	301-496-1653
NIH	National Cancer Institute	301-496-3428
NIH	National Center for Complementary and Alternative Medicine	301-496-4792
NIH	National Center on Minority Health and Health Disparities	301-402-1366
NIH	National Center for Research Resources	301-496-6023
NIH	National Eye Institute	301-451-2020
NIH	National Heart, Lung, and Blood Institute	301-435-0260
NIH	National Human Genome Research Institute	301-496-7531
NIH	National Institute on Aging	301-496-9322
NIH	National Institute on Alcohol Abuse and Alcoholism	301-443-4375
NIH	National Institute of Allergy and Infectious Diseases	301-496-7291
NIH	National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463

PHS AGENCY (LINK TO WEB SITE)	AWARDING COMPONENT (LINK TO WEB SITE)	TELEPHONE NUMBER
NIH	National Institute of Biomedical Imaging and Bioengineering	301-451-4792
NIH	National Institute on Deafness and Other Communication Disorders	301-496-1804
NIH	National Institute of Dental and Craniofacial Research	301-594-4800
NIH	National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834
NIH	National Institute on Drug Abuse	301-443-2755
NIH	National Institute of Environmental Health Sciences	919-541-7723
NIH	National Institute of General Medical Sciences	301-594-4499
NIH	National Institute of Mental Health	301-443-3367
NIH	National Institute of Neurological Disorders and Stroke	301-496-9248
NIH	National Institute of Nursing Research	301-594-6906
NIH	National Library of Medicine	301-496-4621
NIH	Center For Scientific Review	301-435-0715
	Study Section Information	301-435-1115
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	Agency for Healthcare Research and Quality	301-427-1447

Before Submission

You may wish to contact NIH or AHRQ staff with a variety of questions before submitting an application. Each FOA includes names of staff members.

Contact [GrantsInfo](#) and/or the [Division of Receipt and Referral, Center for Scientific Review \(CSR\)](#), [NIH](#):

- To identify Institutes/Centers (ICs) at NIH or other non-NIH agencies and/or a Scientific Review Group (SRG) that might be appropriate for your application. Note requests for assignment to an Institute/Center and/or SRG may be made in a [cover letter](#) at the time of application submission.
- To learn about [grant programs](#).
- To receive advice on preparing and submitting an application (e.g., format, structure).

Contact program staff in the relevant awarding component:

- To determine whether your proposed application topic would fit into the NIH IC's or AHRQ's programmatic area.

- To learn about programmatic areas of interest to the IC or AHRQ.
- To find out about requesting an assignment to an IC.
- To discuss whether you should respond to an RFA.
- To receive scientific guidance on preparing and submitting an application.
- To discuss appropriate fellowship level, particularly predoctoral and senior fellowships.

Contact Scientific Review Officers in the CSR to discuss requesting assignment to a CSR SRG.

After Submission

If the initial assignment to an IC or SRG seems inappropriate, the Fellowship applicant (to be designated as the Program Director/Principal Investigator, or 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 outcomes will create serious breaches of confidentiality in the review process. Reviewers are required to notify the Scientific Review Officer (SRO) 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 your 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 your SRG, conflicts, reviewers that may have bias).

After Peer Review

Feedback to applicants is very important. Once the Fellowship applicant 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 in the Summary Statement.
- To find out the funding status of an application.

A paper copy of the Peer Review Outcome Letter and Summary Statement will not be mailed to the Fellowship applicant 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 AHRQ and other PHS agencies, excluding NIH awards.

1.6 References

Applicants New to NIH: Getting Started

http://grants.nih.gov/grants/useful_links.htm

Award Information and Data

NIH Research Portfolio Online Reporting Tool (RePORT)

<http://report.nih.gov/index.aspx>

NIH Research Portfolio Online Reporting Tool, NIH Reporter (RePORTER).

<http://projectreporter.nih.gov/reporter.cfm>

Contact Information for an AHRQ Staff Person

<http://directory.psc.gov/employee.htm>

Telephone: (301) 427-1364

Contact Information for an NIH Staff Person

<http://ned.nih.gov/>

NIH locator: (301) 496-4000

Electronic Receipt

For additional information on preparing for electronic receipt, see:

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

eRA Commons

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

Institutions and Fellowship applicants are required to register with the eRA Commons. Registered Fellowship applicants can check assignment/contact information, review outcome, and other important information in the Commons. For more details on Commons registration, see [Section 2.2.2](#).

Email: commons@od.nih.gov.

Telephone: 1-866-504-9552 (toll-free) or 301-402-7469; 301-451-5939 (TTY). Business hours are M-F 7am-8pm Eastern Time.

eRA Commons Help Desk: <http://ithelpdesk.nih.gov/era>

Grant Writing Tips and Sample Applications

http://grants.nih.gov/grants/grant_tips.htm

http://grants.nih.gov/grants/grants_process.htm

Grants Information

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

Email: GrantsInfo@nih.gov

Telephone: (301) 435-0714; (301) 451-5936 (TTY)

Grants.gov User Guide

The Grants.gov User Guide is a comprehensive reference to information about Grants.gov. Applicants can download the User Guide as a Microsoft Word document or as a PDF document. The user guide can be accessed at the following address:

<http://www.grants.gov/assets/ApplicantUserGuide.pdf>.

NIH Office of Extramural Research Human Subjects Web site

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

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

Office for 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://olaw.nih.gov>

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 email the SRO identified for the application in the eRA Commons. In order to avoid delays in the e-notification process, it is vital that all Fellowship applicants are registered in the eRA Commons and e-mail addresses are checked periodically for accuracy.

Specific Application: Post Review

Telephone or email the NIH or AHRQ Program Official named in the Summary Statement for the application.

1.7 Authorization

NIH and AHRQ request the information described in these instructions pursuant to the statutory authorities contained in Section 487 of the PHS Act, as amended (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 to review an application and to monitor the awardee's performance.

The statutory authorities for the Fellowship programs are contained in the following:

F30, F31, F32, and F33 Authority: Sections 301(a) and 487 of the PHS Act, as amended (42 USC 241a and 42 USC 288), 42 CFR Part 66.

F05 Authority: Section 307, 42 USC 2421 and 42 CFR Part 63a.

F37 Authority: Section 472, 42 USC 286b-3 and 42 CFR Part 61.

AHRQ Authority: Section 487, Sections 304, 902, and 935 of the PHS Act, 42 USC 242b, 299, and 299c-4 and 42 CFR 67, Subpart A.

1.7.1 Collection of Personal Demographic Data

Federal agencies have a continuing commitment to monitor the operations of its review and award processes to detect, and deal appropriately with, any instances of real or apparent inequities. In addition, Section 403 of the 2007 NIH Reform Act requires NIH to report to Congress specifically on postdoctoral individuals supported on research grants, and section 489 of the PHS Act requires NIH to perform a continuing assessment of research personnel needs. Personal demographic data on PD/PIs and those with a postdoctoral role is vital to comply with these requirements.

NIH and AHRQ collect personal data through the eRA Commons Personal Profile. The data is provided one-time by the individual through a secure, electronic system, is confidential, and is maintained under the Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." When completing the data entry in the Commons Personal Profile, the individual is responsible for providing true, accurate, and complete data. All analyses conducted on date of birth, citizenship, gender, race, ethnicity, disability, and/or disadvantaged background data will report aggregate statistical findings only and will not identify individuals. Declining to provide information does not affect consideration of an application, however, for some applications (e.g., Kirschstein-NRSA and research career development awards) citizenship is required to determine eligibility.

The PHS also requests the last four digits of the Social Security Number (SSN) for accurate identification of individuals and for management of PHS grant programs. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this portion of the SSN. The PHS requests the last four digits of the SSN under Sections 301(a) and 487 of the PHS Act as amended (42 U.S.C. 241a and U.S.C. 288).

1.8 Paperwork Burden

The PHS estimates that it will take approximately 18 hours to complete this application for an individual fellowship. This estimate excludes time for development of the research training 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 (0925-0002). Do not send applications or any materials related to training or career award applications to this address.

2. Process for Application Submission via Grants.gov

Application submission through Grants.gov involves several steps. Access the “Get Started” tab on the Grants.gov Web site (<http://grants.gov>). Some of the steps need only be done one time. Others are ongoing steps that will be necessary for each application submission. Before beginning the application process, you are encouraged to review [Grants.gov](#) and all the resources available there.

2.1 Overview

The following steps must be taken in order to submit a grant application through Grants.gov. Please be sure to complete all steps to ensure that NIH receives the application in a timely manner.

1. Register your organization at Grants.gov. (This is a one-time only registration process for all Federal agencies. If your organization has already completed this step for any Federal agency submission, skip to step #2. If your organization has not completed this step, see [Section 2.2](#) for more details.)
2. Register your organization and the Fellowship applicant (to be designated as the Program Director/Principal Investigator, or PD/PI) in the eRA Commons. The Fellowship applicant is the PD/PI. (This is a one-time only registration process. If your organization has already completed this step, skip to step #3. If your organization has not completed this step, see [Section 2.2](#) for more details.) If the Fellowship applicant has already been registered in the eRA Commons by another organization and assigned the PI role, see [Section 2.2.2.2](#).
3. Find a Funding Opportunity Announcement (FOA) using the [Grants.gov “Apply”](#) feature that reflects use of the SF424 (R&R) forms and electronic submission through Grants.gov. (See [Section 2.4](#) for more details.)
4. Download the associated Application Package from Grants.gov. (Adobe Reader required for download. See [Section 2.3](#) for more details.)
5. Complete the appropriate application components, including all text and PDF attachments. Upload all attachments into the appropriate application component (See [Section 2.6](#) for more details on the requirements for text (PDF) attachments).
6. The completed application should be reviewed through your own organizational review process.
7. Coordinate with an Authorized Organizational Representative (AOR) at the applicant organization to submit the application by the date specified in the FOA. **(Keep a copy locally at the Applicant Organization/Institution.)**
8. Receive the Grants.gov tracking number.
9. After agency validation, receive the agency tracking number (accession number).

10. The Fellowship applicant and Signing Official (SO) complete a verification process in the eRA Commons. (See [Section 2.11](#) for detailed information.)

The following sections explain each step in more detail.

2.2 Registration Processes

2.2.1 Grants.gov Registration

Grants.gov requires a **one-time** registration *by the applicant organization*. Fellowship applicants do not have to individually register in Grants.gov unless they also serve as the Authorized Organizational Representative (AOR) for their institution/organization. If an applicant organization has already completed Grants.gov registration for another Federal agency, they can skip this section and focus on the NIH eRA Commons registration steps noted below. For those applicant organizations still needing to register with Grants.gov, registration information can be found at Grants.gov/GetStarted (<http://www.grants.gov/GetStarted>). While Grants.gov registration is a one-time only registration process, it does involve several steps and will take some time. Applicant organizations needing to complete this process are encouraged to **start early** allowing several weeks to complete all the steps before actually submitting an application through Grants.gov.

The AOR is 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. This individual has the authority to sign grant applications and required certifications and/or assurances that are necessary to fulfill the requirements of the application process. Once this individual is registered, the organization can then apply for any government funding opportunity listed in Grants.gov, including NIH and other PHS agencies grants.

Questions regarding Grants.gov registration should be directed to the Grants.gov Contact Center at telephone: 1-800-518-4726 or by email at support@grants.gov. The Contact Center is available 24 hours a day, 7 days a week.

2.2.2 eRA Commons Registration

The sponsoring organization and the Fellowship applicant (referred to as 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 Fellowship applicants must be registered in the Commons before they can take advantage of electronic submission and retrieval of grant information, such as reviewing grant applications, institute/center assignments, review outcomes, and Summary Statements. Institutional/organizational officials are responsible for registering Fellowship applicants in the eRA Commons. Individuals seeking individual fellowship support should work with their AOR (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 the submittal date of a Grants.gov submission. Failure to register in the Commons and to include a valid PD/PI Commons ID for the Fellowship applicant in the credential field of the Senior/Key Person Profile Component will prevent the successful submission of an electronic application to NIH.

2.2.2.1 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).

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).

This registration is independent of Grants.gov and may be done at any time.

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 for applications to be accepted. In addition, the DUNS number in the Institutional Profile must match that entered in the SF424 (R&R) Cover Component in Section 5, Applicant Information.** This information will be used to generate the electronic grant application image that the Signing Official and the Fellowship applicant will be asked to verify within the eRA Commons. See [Section 2.11](#) for details on the Commons application verification process.

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 AOR/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 your organization has a DUNS number or to find out if the DUNS number you have matches the one in Commons, access the List of Grantee Organizations Registered in NIH eRA Commons (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.

2.2.2.2 Commons Registration for the Fellowship applicant (designated as Program Director/Principal Investigator, or PD/PI)

The individual Fellowship applicant for whom support is being requested is to be designated as the PD/PI on the application, and must also be registered in the Commons. The Fellowship applicant must hold a PI Role **and** be affiliated with the applicant organization. The eRA Commons Postdoctoral Role should **NOT** be used for Individual Fellowship applicants. Only the PI Role will provide the Fellowship applicant with the appropriate access to the application information. **This registration must be done by an organizational official (or delegate) who is already registered in the Commons.** To register Fellowship applicants in the Commons, refer to the NIH eRA Commons System Users Guide (http://era.nih.gov/Docs/COM_UGV2630.pdf).

Once the Fellowship applicant has received email confirming his/her registration within the Commons, the Fellowship applicant must verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. Please have the Fellowship applicant 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 Fellowship applicant and SO need separate accounts in the Commons since both need to 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.

For additional information on how to prepare for electronic submission, see:
<http://era.nih.gov/ElectronicReceipt/preparing.htm>.

Guidance for Affiliating Individual Fellows in the eRA Commons

In October 2006, NIH issued “Guidance to Applicant Organizations about Registering Research Fellows in the eRA Commons” (Notice Number: NOT-OD-07-003; see <http://grants.nih.gov/grants/guide/notice-files/not-od-07-003.html>). The purpose of this Notice is to remind applicant organizations that they should register in the eRA Commons any individual research fellows who are submitting applications to NIH and AHRQ. Many individuals who are submitting Individual Fellowship applications have the unique circumstance of actually submitting an application through a Sponsoring Organization that is different than their current organization. This is perfectly appropriate considering the nature of Individual Fellowship programs. However, this does pose a complexity with respect to eRA Commons registration. Many prospective individual fellows have already been registered in the eRA Commons by their current organization. However, to be able to view the records for an application submitted through a different organization, that individual must also be “affiliated” with the new sponsoring organization. Note a separate eRA Commons registration is NOT required. However, the proposed sponsoring organization must take steps to affiliate the Fellowship applicant.

This process assumes the Fellowship applicant has already been registered in the eRA Commons by another organization and assigned the PI Role. If a Fellowship applicant has not yet been registered in the eRA Commons, they should work with the appropriate officials within the sponsoring organization to be properly registered. When the sponsoring organization handles the initial eRA Commons registration, no further affiliation is required.

To Affiliate a Fellowship Applicant with a Different Sponsoring Organization:

- 1) Fellowship applicant gives Commons user ID and email address to the administrator of the new sponsoring organization. (The email address must be the one that is contained in the Personal Profile for the Fellow.)
- 2) Administrator of the new sponsoring organization logs into the Commons. (The administrator can be the Signing Official, Administrative Official, or the Accounts Administrator.)
- 3) Administrator selects "Administration" tab and then "Accounts" tab.
- 4) Administrator selects "Create Affiliation" tab.
- 5) Administrator enters the Commons User ID and Email address into the appropriate fields and clicks **Submit**.

Note: The account cannot have any other roles attached to it other than the PD/PI and IAR (Internet Assisted Review). For additional information on Creating Affiliations for Users in the eRA Commons, see: <https://commons.era.nih.gov/commons-help/175.htm>.

2.3 Software Requirements

2.3.1 Adobe Reader

In order to access, complete and submit applications, applicants need to download and install the Adobe Reader, version 8.1.1 or later (version 8.1.6 or 9.2 recommended). For minimum system requirements and download instructions, please see the [Grants.gov User Guide](#) or visit http://grants.gov/help/download_software.jsp.

Please note that you must set the Adobe Reader's page layout options to "Continuous" instead of "Single Page" to ensure all features function properly. To do this, choose View > Page Layout, and then choose the "Continuous" option.

2.3.2 Creating PDFs for Text Attachments

NIH and other PHS agencies require all text attachments to the SF424 (R&R) application forms to be submitted as PDF files.

Applicants should prepare text attachments using any word processing program (following the format requirements in [Section 2.6](#)) and then convert those files to PDF before attaching the files to the appropriate component in the application package. (The PDF format is used to preserve document formatting.) Save all files with descriptive file names of 50 characters or less and be sure to only use standard characters in file names: A through Z, a through z, 0 through 9, and underscore (_). Do not use any special characters (example: "&", "-", "*", "%", "/", and "#") or spacing in the file name, and for word separation use underscore (example: "My_Attached_File.pdf") in naming the attachments.

Some type of PDF-creation software is necessary to create the PDF. (The free Adobe Reader *will not create* a PDF.) To assist applicants searching for PDF-creation software, Grants.gov has published the following list of available tools and software: <http://www.grants.gov/assets/PDFConversion.pdf>. Additionally, applicants may find Planet PDF's "Find PDF Software" feature (http://www.planetpdf.com/find_software.asp) useful to browse or search a comprehensive database of free, shareware, or commercial PDF products. Applicants should choose the PDF-creation software that best suits their needs.

Note that all PDF attachments must be submitted as individual files. Although some software packages allow bundling of multiple PDFs into a single file, eRA systems cannot support "Bundling" or "Portfolio" features at this time. Use of these features may result in delays in the review of an application or an application not being reviewed.

It is recommended that, as much as possible, applicants avoid scanning text documents to produce the required PDFs. Instead, NIH recommends producing the documents electronically using text or word-processing software and then converting documents to PDF. Scanning paper documents, without the proper Optical Character Recognition (OCR) process, will hamper automated processing of your application for NIH analysis and reporting.

DISCLAIMER: References to software packages or Internet services neither constitute nor should be inferred to be an endorsement or recommendation of any product, service, or enterprise by the NIH or AHRQ, any other agency of the United States Government, or any employee of the United States Government. No warranties are stated or implied.

2.3.3 Special Instructions for Macintosh Users

With the conversion to Adobe Reader application submissions there are no longer special instructions for Macintosh users.

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 originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the NIH. All submissions to Grants.gov require a FOA. For a list

and brief description of fellowship grant activity codes, see [Part III: Policies, Assurances, Definitions, and Other Information](#).

2.4.1 NIH Guide for Grants and Contracts

The *NIH Guide for Grants and Contracts* (<http://grants.nih.gov/grants/guide>), a weekly electronic publication, 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 NIH and AHRQ Funding Opportunity Announcements

Funding Opportunity Announcements (Program Announcements and Requests for Applications)

An NIH IC or AHRQ may issue a Funding Opportunity Announcement (FOA) in the form of a Program Announcement (PA) or a Request For Application (RFA) soliciting Kirschstein-NRSA Individual Fellowship applications as well as non-NRSA (e.g., F05 and F37). These announcements are available from the sponsoring IC or AHRQ and are issued in the *NIH Guide for Grants and Contracts* (<http://grants.nih.gov/grants/guide/index.html>).

Before preparing an application, applicants should thoroughly review the pertinent FOA noting the research area(s), eligibility requirements, application receipt date, award provisions, and service payback provisions. The applicant is encouraged to contact the Program Officer at NIH or AHRQ prior to submission.

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.

Program Announcement (PA): A formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, 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. NIH may also make funds available through PARs (Program Announcements with special receipt, referral, and/or review considerations) and PASs (Program Announcements with set-aside funds).

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). Read the announcement carefully for

special instructions. The instructions in the announcement may differ from these Fellowship Application Guide instructions, and the instructions in the announcement **always** supersede these Fellowship Application Guide 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.

The NIH Individual Fellowship Funding Opportunity Announcements (FOAs) are also located at http://grants.nih.gov/training/F_files_nrsa.htm.

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.

In reading any FOA in the *NIH Guide for Grants and Contracts*:

- A “release/posted date” refers to the date the FOA is posted on [Grants.gov/Apply](#). An applicant can download the application package on that date and begin filling it out. However, the applicant has to wait until the FOA’s “opening date” to submit the application.
- An application can be submitted anytime between the “opening date” and the “application submission date(s)” noted for AIDS and non-AIDS applications. (Standard dates may apply; check <http://grants.nih.gov/grants/funding/submissionschedule.htm> for details.)
- When you download an application package from Grants.gov, the “expiration date” is pre-populated. Do not go strictly by this date since it may not apply to your particular situation; for instance, it may reflect the submission date for AIDS applications and you may be submitting a non-AIDS application that is due earlier. In this case, the pre-populated date has no bearing on your application and you should not be concerned by it.

2.4.3 Finding a Funding Opportunity Announcement (FOA) for Grants.gov Submission

Implementation of the SF424 (R&R) application and electronic submission through Grants.gov will be announced through specific FOAs posted in the *NIH Guide for Grants and Contracts* and on Grants.gov under “Find Grant Opportunities” (a.k.a. “Find”) and “Apply for Grants” (a.k.a. “Apply”). While all FOAs are posted in Grants.gov Find, not all reference electronic submission via Grants.gov at this time. FOAs posted in Grants.gov Apply reflect those the agency is prepared to receive through electronic Grants.gov submission. Applicants are encouraged to read each FOA carefully for specific guidance on the use of Grants.gov submission.

There are several ways a prospective applicant can find a FOA on Grants.gov.

Using the *NIH Guide for Grants and Contracts*

FOAs in the *NIH Guide for Grants and Contracts* that reference electronic submission via Grants.gov now include a link from the FOA directly to the Grants.gov site where you can download the specific application package. The **Apply for Grants Electronically** button is found in the *NIH Guide* FOA directly under the announcement number. This link is only provided in those announcements involving electronic submission through Grants.gov.

Using “Find Grant Opportunities” (Find) Feature

Grants.gov Find provides general search capabilities. From the “Find Grant Opportunities” page, you may search by clicking on the **Search Grant Opportunities** link. This takes you to a screen providing options for: 1) Basic Search; 2) Browse by Category; 3) Browse by Agency; and 4) Advanced Search. To perform a basic search for a grant, complete the “Keyword Search;” the “Search by Funding Opportunity Number;” **OR** the “Search by CFDA Number” field; and then click the **Search** button below.

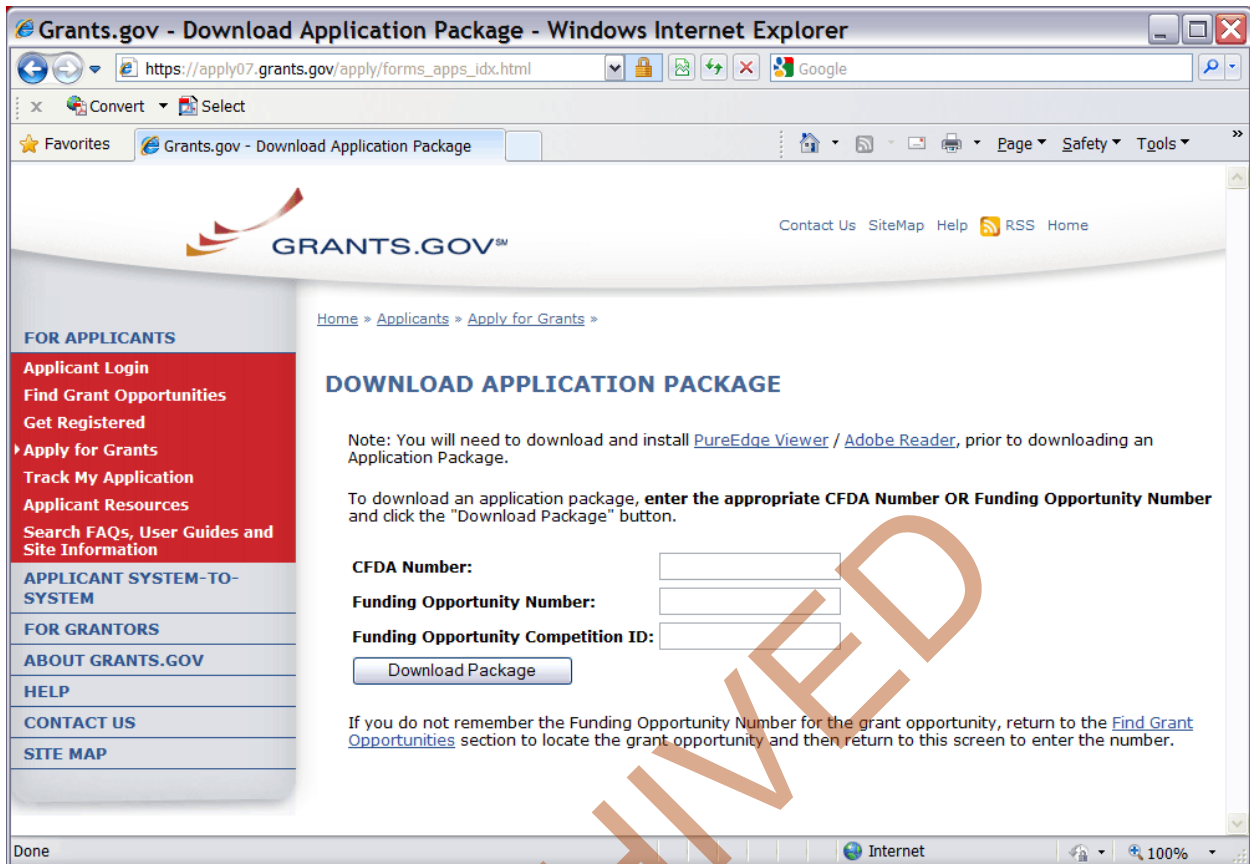
Note that NIH has made it easier for applicants by adding a button (**Apply for Grant Electronically**) to the *NIH Guide for Grants and Contracts* announcements that allows applicants to access the Grants.gov application package directly from the *NIH Guide*. See the preceding paragraph “Using the *NIH Guide for Grants and Contracts*” for more details.

Access Search Tips for helpful search strategies, or click the **Help** button in the upper right corner of Grants.gov to get help with the Search screen.

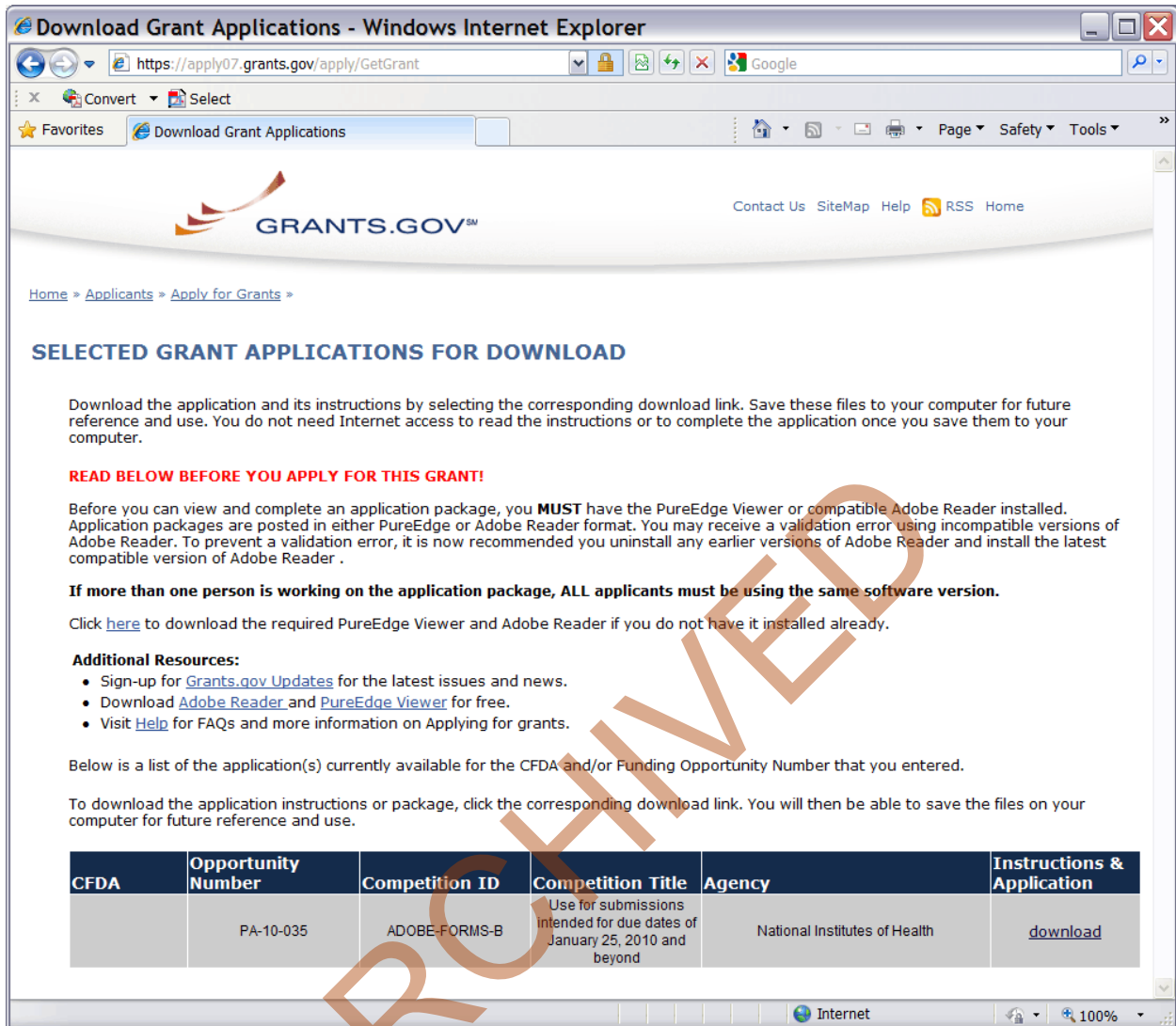
Once you find an opportunity for which you wish to apply, you may initiate the application download process immediately by selecting the “How to Apply” link that appears on the FOA synopsis page. Or you may elect to initiate the application download at a later time. In this case, you should record the Funding Opportunity number or CFDA number and enter it manually later on the Download Application Packages screen in the [Grants.gov/Apply](https://www.grants.gov/Apply) section of this site.

Using “Apply for Grants” (Apply) Feature

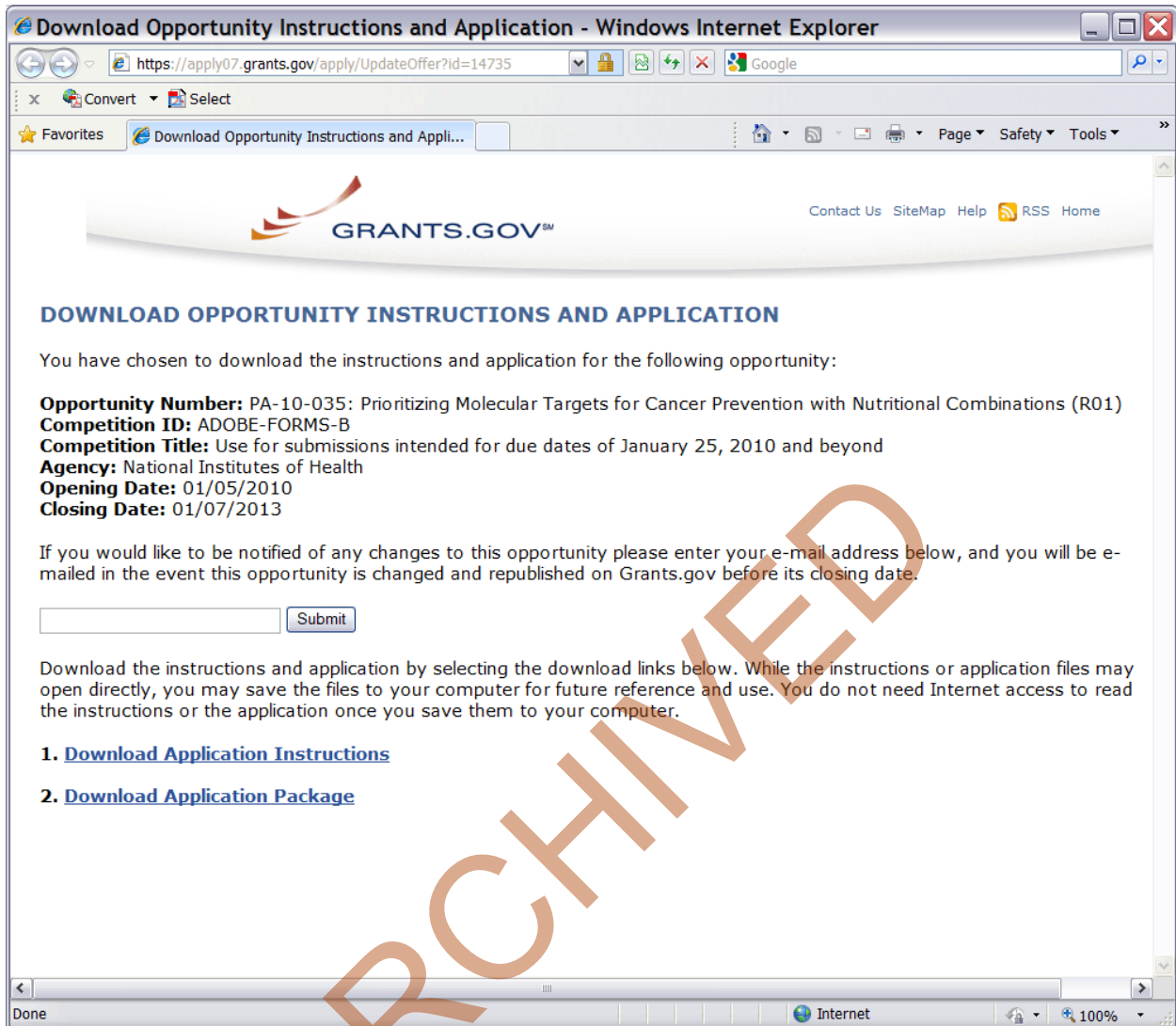
If you know the specific funding opportunity number, a more direct route is to use the “Apply for Grants” feature. From the Grants.gov home page, select “Apply for Grants” and follow the steps provided. “Step 1” allows you to download an application package by inserting a specific Funding Opportunity Number (FOA). If you do not know the specific Funding Opportunity Number there is a link that will take you back to the Find Grant Opportunities page.



A Funding Opportunity Number is referenced in every announcement. It may be called a Program Announcement (PA) Number or a Request for Application (RFA) Number. Enter this number in the Funding Opportunity Number field and click **Download Package**. This takes you to a “Selected Grant Applications for Download” screen.



If you searched only on a specific opportunity number, only one announcement is provided in the chart. Click the corresponding **download** link to access the actual application form pages and instruction material. The following screen appears:



To access the instructions, click **Download Application Instructions**. For NIH and AHRQ opportunities using this Application Guide, this action will download a document containing a link to the NIH Web site where the most current set of application instructions is available (<http://grants.nih.gov/grants/funding/424/index.htm>). Applicants are encouraged to check this site regularly for the most current version.

To access the form pages, click **Download Application Package**. [Section 2.5](#) provides specific information regarding the components of an Application Package. [Section 3](#) provides additional instructions for properly using a package.

On the Download Opportunity Instructions and Applications screen you will be given an opportunity to provide an e-mail address if you would like to be notified of any changes to this particular opportunity. Applicants to NIH and other PHS agencies are strongly encouraged to complete this information. The agency can then use it to provide additional information to prospective applicants.

Note: if multiple CFDA numbers are cited in the FOA, the Download Opportunity Instructions and Applications screen may pre-fill a CFDA number and description that may not correspond to the Institute/Center of interest to you; or the CFDA information may not appear at all. In either case, do not be concerned since the Center for Scientific Review, NIH does not use the CFDA number for assignment

of the application. Be assured the correct CFDA number will be assigned to the record once the appropriate IC assignment has been made.

2.5 Components of an Application to NIH or AHRQ

The SF424 (R&R) form set is comprised of a number of components, each listed in the table below as a separate “document.” In addition to these components, NIH and AHRQ Fellowship applicants will also complete the PHS Fellowship Supplemental Form.

Table 2.5-1. Components of an NIH or AHRQ Application

DOCUMENT	REQUIRED	OPTIONAL	INSTRUCTIONS
SF424 (R&R) Cover	X		Section 4.2
SF424 (R&R) Project/Performance Site Locations	X		Section 4.3
SF424 (R&R) Other Project Information	X		Section 4.4
SF424 (R&R) Senior / Key Person Profile(s) (Expanded)	X		Section 4.5
PHS Cover Letter	X *		Section 5.2
PHS Fellowship Supplemental Form	X		Section 5.3

* Fellowship applicants are required to include a cover letter with the application. The cover letter must contain the same list of referees (including name, departmental affiliation, and institution) that is included in the Other Project Information Component Item 12, Other Attachments. If the application is submitted late, the cover letter must also include an explanation for the late submission. In the cover letter applicants are encouraged to request assignment to a particular NIH institute or Center and a specific SRG, which can be found in Table 1.4-1 PHS Agency Contact Table.

NIH and AHRQ Fellowship application submissions must include the PHS Fellowship Supplemental Form (see [Section 5.3](#)). All required and optional forms for electronic submission listed above are available through Grants.gov and should be downloaded from the FOA being applied to. Do not use any forms or format pages from other sources; these may include extraneous headers/footers or other information that could interfere with the electronic application process.

2.6 Format Specifications for Text (PDF) Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff.

NIH and other PHS agencies require all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted below. Failure to follow these requirements may lead to rejection of the application during agency validation or delay in the review process. (See [Section 2.3.2](#) for more information on creating PDFs.)

Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. Additional tips for creating PDF files can be found at http://era.nih.gov/ElectronicReceipt/pdf_guidelines.htm.

When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document

after it has been attached, you **must** delete the previous attachment and then reattach the revised document to the application form. Use the **View Attachment** button to determine if the correct version has been attached.

File Name

Save all files with descriptive file names of 50 characters or less and be sure to only use standard characters in file names: A through Z, a through z, 0 through 9, and underscore (_). Do not use any special characters (example: "&", "-", "*", "%", "/", and "#") or spacing in the file name, and for word separation use underscore (example: "My_Attached_File.pdf") in naming the attachments.

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.

Paper Size and Page Margins

Use *standard paper size (8 1/2" x 11)*.

Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, including the 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.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

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

You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

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.

Page Limits

Although many of the sections of this application are separate text (PDF) attachments, page limits referenced in these instructions and/or funding opportunity announcement must still be followed. Agency validations will include checks for page limits. Some accommodation will be made for sections that when combined must fit within a specified limitation. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they do not replace the validations conducted by NIH staff. Applications found not to comply with the requirements may lead to rejection of the application during agency validation or delay in the review process.

All applications for NIH and AHRQ funding must be self-contained within specified page limits. Unless otherwise specified in an NIH solicitation, Internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity.

The biographical sketch attachment for the PD/PI-applicant fellow, sponsor, co-sponsor(s), dissertation advisor(s) and other significant contributors when applicable are limited to 4 pages per person. See Biographical Sketch instructions in [Section 4.5 Senior/Key Person Profile \(Expanded\) Component](#).

For the applicant fellow, see Fellowship Application Biographical Sketch Format Page at <http://grants.nih.gov/grants/funding/424/applicant-fellowbiosketch.doc>. A completed example is found at: <http://grants.nih.gov/grants/funding/424/applicant-fellowbiosketchsample.doc>.

For the sponsor, co-sponsor(s), dissertation advisors(s) and other significant contributors, see Biographical Sketch format at http://grants.nih.gov/grants/funding/424/SF424R-R_biosketch_VerB.doc. A completed example is found at: http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerB.doc.

Observe the page number limits given in Table 2.6-1. The table below is in the order of information as it appears in the instructions.

Table 2.6-1. Page Limitations and Content Requirements

SECTION	PAGE LIMIT (MAXIMUM PAGE LIMIT LISTED)	CONTENT
Other Project Information Component Other Attachments 12.A Sponsor and Co-Sponsor Information	6 pages total	See Instructions in Section 4.4
PHS Fellowship Supplemental Form B. Research Training Plan Introduction - New applications - Resubmission applications	Not to be submitted 1 page with resubmission	See Instructions in Section 2.7
Research Training Plan B.2 Specific Aims B.3 Research Strategy Sections B.4 & 5	1 page 6 pages total No limit	Text including all figures, charts, tables, and diagrams.
Human Subjects Sections B.6 through 12	No limit	See Instructions in Section 5.3
Other Research Training Plan Sections Sections B.13 through 16	No limit	See Instructions in Section 5.3

SECTION	PAGE LIMIT (MAXIMUM PAGE LIMIT LISTED)	CONTENT
Respective Contributions Section B.17	1 page	See Instructions in Section 5.3
Selection of Sponsor and Institution Section B.18	1 page	See Instructions in Section 5.3
Responsible Conduct of Research Section B.19	1 page	See Instructions in Section 5.3
PHS Fellowship Supplemental Form C. Additional Information Applications for Concurrent Support Section C.6	1 page	See Instructions in Section 5.3
Goals for Fellowship Training and Career Section C.7	1 page	See Instructions in Section 5.3
Activities Planned Under this Award Section C.8	1 page	See Instructions in Section 5.3
Doctoral Dissertation and Other Research Experience Section C.9	2 pages	See Instructions in Section 5.3
PHS Fellowship Supplemental Form E. Appendix	No page limits. (Grants.gov defaults to a maximum of 10 separate attachments)	New requirements effective 1/3/2007. See Instructions for specifics. See PHS Fellowship Supplemental Form, Section 5.3
FOAs (PA, RFA)	Page limitations specified in the NIH Guide FOAs take precedence.	See specific instructions in FOAs published in the NIH Guide

2.7 Resubmission Applications

For all original new (i.e. never submitted) individual fellowship applications intended for the April 2009 due dates 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 April 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.

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

There are five requirements for a Resubmission application:

- **The Summary Statement must be available in the eRA Commons** (<http://commons.era.nih.gov/commons/>).
- The Fellowship applicant must make significant changes to the application.
- An Introduction of no more than one page 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. Use item B.1., Introduction to Application, of the PHS Fellowship Supplemental Form to provide this information. The Introduction may not exceed one page unless the FOA specifies otherwise.
- The substantial scientific changes must be marked in the text of the Research Training Plan 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 in the Research Strategy/Approach should incorporate work completed since the prior version of the application was submitted.
- New Letters of Reference must be submitted electronically through the eRA Commons at <https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp> using the appropriate Fellowship Reference Form, providing an up-to-date evaluation of the Fellowship applicant's potential to develop as an independent and productive researcher, and the continued need for additional supervised research experience.

The Research Strategy section (PHS Fellowship Supplemental Form – Item 3) should incorporate work completed (if any) since the prior version of the application was submitted.

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 the fellowship mechanism is a research training application with emphasis in the research training plan, demonstration of the institutional environment to prepare a research training candidate and documentation of evidence for the potential of the fellow to become an independent investigator. After two reviews (original plus one resubmission) any subsequent fellowship application (now a new application with a different number) is expected to be substantially different in the mentoring plan and the content and scope of planned research training 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 Strategy should produce a significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all portions of the Specific Aims and

Research Strategy. 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.

Reference Letters for Resubmission Application: Applicants must arrange for the resubmission of three reference letters. See [Reference Letter instructions](#) in Part I, Section 5.4 for additional details.

2.8 Revision Application

This section is generally not applicable to individual fellowships supported by NIH and AHRQ.

2.9 Similar, Essentially Identical, or Identical Applications

Submissions of identical applications to one or more components of the PHS are not allowed.

The NIH will not accept identical or essentially identical research training applications submitted by different applicant organizations. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the Fellowship applicant (PD/PI) are the original work of the sponsor investigator 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. 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 not be reviewed.

2.10 Submitting Your Application Via Grants.gov

The Applicant Organizational Representative (AOR) registered in Grants.gov is the only official with the authority to actually submit applications through Grants.gov. Therefore, the Fellowship applicant (PD/PI) will need to work closely with their AOR to determine that all the necessary steps have been accomplished prior to submitting an application. This includes any internal review process required by the applicant organization.

Before starting the final submission step, **applicants are encouraged to save a copy of the final application locally**. Once you have properly completed all required documents and attached any required or optional documentation, click on the **Check Package for Errors** button to ensure that you have successfully completed all required data fields. If any of the required fields are not completed you will receive an error notice which will indicate where revision is needed within your package. Correct any errors or if none are found, save the application package. The **Save & Submit** button will now become active and clicking this button will begin the application submission process. Only after the package has been saved with no errors will the **Save & Submit** button become active. The application package must then be saved once more before the submission process begins. Only an AOR will be able to perform the submit action, and they will be taken to the applicant login page to enter the Grants.gov username and password that was established in the Register with Grants.gov process (if not connected to the internet you will be instructed to do so).

Once logged in, the application package will be automatically uploaded to Grants.gov. A confirmation screen will appear once the upload is complete and a Grants.gov Tracking Number will be provided on

this screen. Applicants should record this number so that they may refer to it should they need to contact Grants.gov Customer Support or the eRA Commons Help Desk.

For additional information, access [Grants.gov/Submit Application Package](http://grants.gov/SubmitApplication) (<http://grants.gov/SubmitApplication>).

Applicants should be aware that on-time submission of an application is currently a two-step process: 1) the application is accepted by Grants.gov on or before 5 p.m. Local time of the applicant organization on the submission date, and 2) reviewed within two business days of the image being available in the eRA Commons (the image is available only once all errors are corrected).

Once an application package has been successfully submitted through Grants.gov NIH provides applicants a two-day error correction window to correct any eRA identified errors or warnings before a final assembled application is created in the eRA Commons. The standard error correction window is two (2) business days, beginning after the submission deadline and excluding weekends and Federal holidays. All errors must be corrected to successfully complete the submission process. Warning will not prevent the application from completing the submission process.

Please note that the following caveats apply:

- Initial application must be “on-time.”
- The AOR/institution is expected to enforce that application changes made within the error correction window are restricted to those necessary to address system-identified errors/warnings. NIH may reject an application that included additional changes.
- Proof of “on-time” submission (e.g., Grants.gov timestamp and tracking number) and a description of all changes made within the window must be documented in the PHS398 Cover Letter component of the application.

Note: In some extenuating circumstances, the error correction window may be extended beyond the standard two business days. The NIH Guide to Grants and Contracts (<http://grants.nih.gov/grants/guide/index.html>), Electronic Submission Program e-mail lists, and the Electronic Submission web site (<http://era.nih.gov/ElectronicReceipt/>) will be the primary vehicles used to communicate error-correction window extensions. Any changes or updates will also be noted in NIH Guide Notice NOT-OD-08-018 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-018.html>).

2.11 After You Submit Your Application Via Grants.gov

The Authorized Organizational Representative (AOR) can use Grants.gov to check the status of an application at any time. Note that Grants.gov requires a user login and password. To check the status of an application, go to <https://apply07.grants.gov/apply/checkApplStatus.faces>.

Once an application has been submitted via Grants.gov, several emails are generated by Grants.gov and sent to the AOR (also known as the Signing Official [SO]) named in the grant application indicating a Grants.gov tracking number that is assigned to the submission:

- 1) **Submission Receipt:** An email is sent indicating your application has been received by Grants.gov and is currently being validated.
- 2) **Submission Validation Receipt:** An email is sent indicating your application has been received and validated by Grants.gov and is being prepared for Grantor agency retrieval.
- 3) **Grantor Agency Retrieval Receipt:** An email is sent indicating your application has been retrieved by the Grantor agency.

- 4) Agency Tracking Number Assignment for Application: An email is sent indicating your application has been assigned an Agency Tracking Number.

If the AOR/SO has not received a confirmation message from Grants.gov within 48 hours of submission, please contact:

Grants.gov Contact Center
Telephone: 1-800-518-4726
Email: support@grants.gov

At that point, the application will be scheduled for download into the eRA system for agency validation. It is imperative that the email address provided in blocks 14 for the Fellowship applicant (PD/PI) and 19 for the AOR/SO on the SF424 (R&R) Cover component be current and accurate. Once agency validation is completed, an agency notification (not Grants.gov) will be emailed to the Fellowship applicant and AOR/SO named in the application.

This email notification will inform the Fellowship applicant and AOR/SO that the application has been received and processed by the agency and will indicate whether any errors or warnings resulted during the validation process. The Fellowship applicant and AOR/SO will be invited to log on the eRA [Commons](#), to view the assembled application or review the list of warnings/errors that were encountered during the validation process.

If there were no validation errors, this email notification will also inform the Fellowship applicant and AOR/SO of an agency accession number, which represents the “agency tracking number.” This number replaces the Grants.gov tracking number that was assigned when the application was first submitted. The Grants.gov system will indicate that the agency tracking number has been assigned, and will reflect both numbers. In subsequent interaction with the eRA Commons, however, it is the agency accession number that will be used to refer to the application, not the Grants.gov tracking number.

The eRA system will make every effort to send an email to the Fellowship applicant and AOR/SO summarizing download and validation results. However, since email can be unreliable, applicants are strongly encouraged to periodically check on their application status in the Commons.

Once an application package has been successfully submitted through Grants.gov, all errors are corrected and an application has been assembled by the eRA Commons, Fellowship applicants and AORs/SOs will have two weekdays (Monday – Friday, excluding Federal holidays) to view the application. If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two weekdays, excluding Federal holidays. (Note, the previous PI & SO Verification steps have been eliminated effective with submissions made on/after May 10, 2006.)

If, however, it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to “Reject” the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications.

The “Reject” feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays (Monday – Friday, excluding Federal holidays) if no action is taken. Some warnings may need to be addressed later in the process.

Fellowship applicants should work with their AOR/SO to determine when the “Reject” feature is appropriate.

To view the assembled application the AOR/SO should:

1. Login to the eRA Commons (<https://commons.era.nih.gov/commons/>) with your Signing Official (SO) account.
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions** on the left-hand side of the screen.
4. Search for your application by date received, grants.gov tracking number, or accession number, to view a hitlist of available applications.
5. When you find the appropriate application, click the accession number in the **Application ID** column to view the status information screen.
6. Click **e-Application** from the Other Relevant Documents section to view the assembled application.

Note: The SO can Reject the application by clicking on the **Reject eApplication** hypertext link from the Action Column of the search hitlist.

To view the assembled application the Fellowship applicant should:

1. Login to the eRA Commons (<https://commons.era.nih.gov/commons/>) with your Fellowship applicant (PI) account.
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions** near the top of the screen to view a hitlist of available applications.
4. When you find the appropriate application, click the accession number in the **Application ID** column to view the status information screen.
5. Click **e-Application** from the Other Relevant Documents section to view the assembled application.

2.12 Correcting Errors

Prior to a specified submission date, applicants may make corrections and resubmit an application through Grants.gov. After a specified submission date, if applicants make corrections and resubmit, the application will be considered late. In this case, applicants *must* include a cover letter explaining the reasons for the delay. Also see [Section 2.14](#) for additional information on submission dates.

If validation errors or warnings result from the validation process, the Fellowship applicant and AOR/SO will be issued an email instructing them to log on to the eRA Commons to review the list of warnings/errors that were encountered during the validation process. The eRA system will make every effort to send an email to the Fellowship applicant and AOR/SO indicating whether errors or warnings were detected. However, since email can be unreliable, applicants are strongly encouraged to periodically check on their application status in the eRA Commons, so that any errors or warnings can be resolved in the timeliest manner possible.

Please be aware of the distinction between *errors* and *warnings*. The word *error* is used to characterize any condition which causes the application to be deemed unacceptable for further consideration. Generally, errors will indicate significant inaccuracies, inconsistencies, omissions, or incorrect formatting that have been identified in the body of the application. Conversely, the word *warning* characterizes any condition that is acceptable, but worthy of bringing to the applicant's attention. It is at the applicant's discretion, whether a warning condition requires any action.

Error conditions must be corrected, and then the application may be submitted as a changed/corrected application (as outlined below) in order for the application to be accepted. Please note that if validation has identified *warnings only*, then the Fellowship applicant and SO will be allowed to view the application. Warnings do not require any action or submission of a changed/corrected application at this time. However, please be aware that some warnings may need to be addressed later in the process or review stages. Failure to comply with stated NIH policies can also result in a submitted application being returned to the applicant without review. For this reason, applicants are strongly encouraged to review all warnings, to ensure that they require no further attention and that they are satisfied with the validation results. If desired, warnings can be corrected in the same manner as errors.

A changed/corrected application may also be submitted if the PDF image, as viewed in the eRA Commons is incomplete or inaccurate from that submitted.

Errors and warnings may be reviewed in the Commons by performing the following steps:

1. After the application has been downloaded from Grants.gov and validated by the system, access the eRA Commons (<https://commons.era.nih.gov/commons/>).
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions** on the left-hand side of the screen.
4. Search for your application by date received, grants.gov tracking number, or accession number.
5. A hitlist of application numbers is displayed. If the application was validated with warnings only, or without encountering any problems whatsoever, then it is identified in the hitlist by its NIH accession number (e.g., “AN:2911064”). This is the same number that Grants.gov displays, and refers to as the “agency tracking number.”

If any *errors* were identified during validation, then the application still appears in the hitlist, but in this case it is identified by its Grants.gov tracking number (e.g., “GRANT87654321”). This is the number that Grants.gov assigned to your application at the time of submission.

6. When you find the appropriate application in the hitlist, click its application link.
7. The error/warning page appears, and you are then able to review all conditions that were identified during validation. If only *warnings* were identified, you may elect to take action and resubmit; however you may accept the warnings and proceed to view the application, as described earlier.

To correct errors and resubmit the application:

1. Make whatever corrections are necessary, wherever appropriate. Most often this means that you have to edit the data within the application forms to correct whatever problem or inconsistency that was noted.
2. Check the “Changed/Corrected Application” box in block 1 of the SF424 (R&R) Cover component.
 - If submitting after the submission date, include an explanation in the Cover Letter Component.
 - When you check the Changed/Corrected Application box, Item 4. Federal Identifier becomes a required field.
 - When submitting a Changed/Corrected Application for a “New” Type of Application (Item 8 = New), in the Federal Identifier field (Item 4) enter the Grants.gov tracking number for the previous application that you are correcting. If you are unable to recall the Grants.gov tracking number, enter “N/A.”

- When submitting a Changed/Corrected Application for a “Resubmission” or “Renewal” Type of Application (Item 8 = Resubmission or Renewal), in the Federal Identifier field (Item 4) enter the IC and serial number of the previously assigned application/award number (e.g., CA987654).
- Do not use the Changed/Corrected Application box to denote a submission of a revised or amended application. That will be indicated in item 8, Type of Application.

3. Have the AOR/SO submit the revised application package to Grants.gov again.

The same email notifications will be issued once the agency has downloaded and validated the re-submitted application and the Fellowship applicant and AOR/SO will once again be required to log on to the Commons either to view the application, or to review the errors that were encountered during validation.

The application will only be assigned for scientific review once errors are resolved.

In addition to the validations performed by the eRA system, further administrative review will be conducted by agency staff. The Fellowship applicant and/or the applicant organization may be contacted for further corrections/clarifications.

2.13 Submission of Supplementary or Corrective Information

Applicants may have the need to submit supplementary or corrective material after the submission date, such as revised biographical sketches, updated or supplemental pages, letters of support or collaboration and publications (accepted but not yet published, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html>). Acceptance of additional materials prior to peer review is at the discretion of the NIH SRO. Additional materials should be sent as a PDF attachment to an e-mail. E-mail communication is preferred. If e-mail is not feasible, please send in a hard copy.

The original application is kept intact; any additional material is sent separately to reviewers. Updated or supplemental grant application materials used in the peer review process will be retained as part of the official grant file and remain part of the permanent record for that application.

The additional materials must be submitted to the NIH SRO with the consent of the applicant organization’s designated AOR/SO. NIH require that the applicant organization include the AOR in the correspondence; the AOR is not necessarily required to submit the application materials. It is acceptable for the Fellowship applicant to send such materials with the concurrence of the AOR (designated institutional signing official). Materials sent without evidence of such concurrence will not be accepted.

The deadline for receipt of additional materials is one month (30 calendar days) prior to the peer review meeting. FOAs may provide stricter or more lenient guidance.

After the initial peer review phase is completed, the NIH Chief Grants Management Officer is the NIH official responsible for accepting additional materials. Most of the materials submitted after the initial peer review can be submitted as part of the Just-In-Time process (see [Part III.1.7](#)).

See also <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-082.html> and [NIH Best Practices Guidance for Accepting Additional Grant Application Materials](#).

2.14 Application Submission Dates

For submission of applications to NIH, each FOA includes an Opportunity Open Date and an Opportunity Close Date. Many announcements, including those using the “Standard Submission Dates” noted in Table 2.15-1 below, include multiple submission/receipt dates and are active for several years. These announcements are posted in Grants.gov and the NIH Guide to Grants and Contracts showing an

Open/Close period that spans the entire active period of the announcement. Applicants should read the Funding Opportunity Announcement carefully for specific submission/receipt dates. If specific dates are not referenced in the announcement, applicants should refer to the Standard Submission Dates for Competing Applications noted in Table 2.15-1.

Applications submitted for the Standard Submission Dates listed in Table 2.15-1 are considered on time if they are submitted to Grants.gov on or before 5 p.m. local time on the appropriate date listed. Applications submitted to FOAs with a single submission date are considered on time if they are submitted to Grants.gov on or before 5 p.m. local time on the appropriate date listed. Applications submitted for Special Receipt Dates are considered on time if they are submitted to Grants.gov on or before 5 p.m. local time on the Grants.gov posted Closing Date. Requests for Applications (RFAs) and Program Announcements with Special Referral Considerations (PARs) with special receipt dates always must be received by Grants.gov on the dates designated in the announcement.

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 submitted on or before the following business day.

Late Applications. Permission for a late submission is not granted in advance. In rare cases, late applications will be accepted but only when accompanied by a cover letter that details the compelling reasons for the delay. While the reasons are sometimes personal in nature, an objective evaluation of their merit requires that some details be provided. Late applications have been accepted for reasons such as: death of an immediate family member of the Fellowship applicant, sudden acute severe illness of the Fellowship applicant or immediate family member, and large scale natural disasters.

NIH will consider accepting late applications based on the acceptability of the explanation and the processing time required for two different kinds of submission/receipt dates.

- **Regular Standard Submission/Receipt Dates:** To be considered applications must be received at the NIH within two weeks of the standard submission date.
- **Expedited Standard Submission/Receipt Dates:** To be considered applications must be received at the NIH within one week of the standard submission date.
- NIH does not expect to accept any applications received beyond the window of consideration.

The windows of time for consideration of late applications have been carefully chosen so that the late applications can be processed with the cohort of on-time applications. In all cases, when the regular standard submission date or expedited submission date falls on a weekend or federal holiday and is extended to the next business day, the window of consideration for late applications will be calculated from that business day. Note that the late window always ends in a receipt (not submission) date.

If an application is submitted late, use the optional PHS Cover Letter component to provide specific information on the timing and nature of the cause of the delay and include this component with the completed application. No other documentation is expected. Late applications are evaluated on an individual basis considering the reasons provided. Contacting the [Division of Receipt and Referral, Center for Scientific Review \(CSR\), NIH](#) in advance will not influence the acceptance of a late application.

Related Guide Notice:

- NOT-OD-08-027 NIH Policy on Submission of Late Applications at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-027.html>; and

2.15 Submission, Review and Award Cycles

The NIH submission, review, and award schedule for Individual Fellowships is provided at this Web site: <http://grants.nih.gov/grants/dates.htm>:

Application Assignment Information

Competing grant applications that have been successfully submitted through Grants.gov (including correcting all errors and the grant application assembled by the eRA Commons system) will be processed through the Division of Receipt and Referral, CSR, NIH unless otherwise stated. The application will be assigned to an appropriate Scientific Review Group and awarding component(s). Assignment is based on the scientific content of the application using established referral guidelines. Business rule validations are conducted by the system as well as NIH staff.

Assignment to Review Group. The Center for Scientific Review (CSR) will assign appropriately completed applications to the Scientific Review Groups (commonly referred to as “SRGs” or “study sections”) that will perform the scientific/technical merit review. The CSR lists a Roster Index for Fellowship Study Sections http://www.csr.nih.gov/Roster_proto/Fellowship_section.asp, and you may suggest a specific group in the PHS Cover Letter component.

Assignment to Relevant Potential Awarding Component(s) (ICs). In addition, CSR will assign each application to the agency awarding component that is the potential funding component. When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two or more awarding components, CSR may assign your application to all such components. The component that has the most relevant program responsibility is designated as the primary assignee. The other components that have an interest in your application are designated as secondary assignees. If your application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignees will be given the opportunity to do so. Although these suggestions will be taken into consideration, the final determination will be made by the agencies participating in this solicitation.

After the submission date, usually within two (2) weeks, the Fellowship applicant and the sponsoring organization’s authorized official will be able to access in the eRA Commons and view the following information regarding the grant application

- Application assignment number
- Name, address, and telephone number of the SRO (if the review takes place in CSR) of the Scientific Review Group to which the application has been assigned for peer review; and
- Assigned Institute/Center information.

Review outcome and other important information are also available in the Commons.

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; TTY (301) 451-5936. If there is a change in assignment, you will receive a notification and the change will be reflected in the eRA Commons.

Applicant investigators 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 your application is complete, applicant investigators must direct all questions to the SRO. 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 Finding Help for Grants.gov Registration or Submissions

If help is needed with the Grants.gov registration process or with the technical aspects of submitting an application through the Grants.gov system, check first the resources available at Grants.gov (<http://grants.gov/>).

Grants.gov customer support is also provided by the following office:

Grants.gov Program Management Office
200 Independence Avenue, SW
HHH Building, Room 739F
Washington, DC 20201

Grants.gov Helpdesk: support@grants.gov

Grants.gov Contact Center Phone Number: 1-800-518-4726

The Contact Center is available 24 hours a day, 7 days a week.

2.16.2 Finding Help for the eRA Commons Registration or eRA Commons Validation Processes

If help is needed with the eRA Commons registration process for the applicant organization and PD/PIs or with the application validation process in the Commons after submission through Grants.gov, check first the resources available at Electronic Submission of Grant Applications (<http://era.nih.gov/ElectronicReceipt/>).

eRA Commons customer support is also provided by the eRA Commons Helpdesk:

eRA Web site: <http://era.nih.gov>

eRA Commons Web site: <https://commons.era.nih.gov/commons/index.jsp>

eRA Commons Helpdesk Email: 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 this application instruction guide, help is still needed in preparing the application, contact GrantsInfo:

GrantsInfo Phone: 301-435-0714
301-451-5936 (TTY)

GrantsInfo Email: GrantsInfo@nih.gov

3. Using the Grant Application Package

This section describes the steps an applicant takes once the appropriate FOA (see [Section 2.4](#)) has been located and the corresponding grant application package has been successfully downloaded.

3.1 Verify Grant Information

When you select a funding opportunity in Grants.gov Apply, verify that the information shown in the Grant Application Package screen corresponds to the funding opportunity for which you wish to apply. Grants.gov auto-populates the following information:

- Opportunity Title
- Offering Agency
- CFDA Number
- CFDA Description
- Opportunity Number
- Competition ID
- Opportunity Open Date
- Opportunity Close Date
- Agency Contact

Save & Submit Save Print Cancel Check Package for Errors

GRANTS.GOV™

Grant Application Package

Opportunity Title: Prioritizing Molecular Targets for Cancer Prevention wi

Offering Agency: National Institutes of Health

CFDA Number:

CFDA Description:

Opportunity Number: FA-10-045

Competition ID: ADOBE-FORMS-E

Opportunity Open Date: 01/05/2010

Opportunity Close Date: 01/07/2013

Agency Contact:
Grants Info
Grants Information
E-mail: GrantsInfo@nih.gov
Phone: 301-435-0714

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

CFDA Number Field: Many FOAs include multiple CFDA (Catalog for Domestic Assistance) numbers. When this is the case, the CFDA Number and CFDA Description fields will appear blank in the Grants.gov Grant Application Package screen shown above. The appropriate CFDA number will be automatically assigned once the application is assigned to the appropriate agency awarding component.

Opportunity Open Date & Close Date Fields: Many FOAs posted by NIH and AHRQ include multiple submission/receipt dates and are active for several years. These announcements are posted in Grants.gov showing an Open/Close period that spans the entire active period of the announcement. Applicants should read the funding opportunity announcement carefully for specific submission/receipt dates. If specific

dates are not referenced in the announcement, NIH applicants should refer to the submission, review, and award schedule for Individual Fellowships provided at <http://grants.nih.gov/grants/dates.htm>. Applications submitted after a posted submission date will normally not be held over into the next review cycle. Instead, the Fellowship applicant will be notified and will have to submit the application again. See [Part I, Section 2.14](#) of this Guide for more information on the late application policy.

3.2 Enter the Name for the Application

Enter a name for the application in the Application Filing Name field (this is a required field). This name is for use solely by the applicant for tracking the application through the Grants.gov submission process. It is not used by the receiving agency.

Note that unless otherwise specified in the FOA, Fellowship applications are submitted by institutions on behalf of the Fellowship applicant.

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

* Application Filing Name:

3.3 Open and Complete Mandatory Documents

Open and complete all of the documents listed in the Mandatory Documents box. **Complete the component titled SF424 (R&R) first.** Data entered in this component populates other mandatory and optional forms where applicable.

Mandatory Documents		Mandatory Documents for Submission
SF424 (R & R) Project/Performance Site Location(s) Research And Related Other Project Information Research And Related Senior/Key Person Profile PHS 398 Cover Page Supplement PHS 398 Research Plan PHS 398 Checklist	Move Form to Complete => Move Form to Delete <=<	
		<input type="button" value="Open Form"/>

To open an item:

1. Click the document name in the Mandatory Documents box.
2. Click **Move Form to Complete**.
3. Click the document name in the Mandatory Documents for Submission box and click **Open Form**.
4. To remove a document from the Mandatory Documents for Submission box, click the document name to select it and then click the **Move Form to Delete** box. This returns the document to the Mandatory Documents box.

3.4 Open and Complete Optional Documents

These documents can be used to provide additional information for the application or may be required for specific types of grant activities. Information on each of these documents is found later in these instructions.

<p>Optional Documents</p> <p>PHS Cover Letter PHS 398 Modular Budget Research & Related Budget R & R Subaward Budget Attachment(s) Form</p>	<p>Move Form to Submission List <input type="button" value="=>"/> Move Form to Delete <input type="button" value="<="/></p>	<p>Optional Documents for Submission</p> <div style="border: 1px solid black; height: 60px; width: 100%;"></div>
<input type="button" value="Open Form"/>		

3.5 Submitting the Application via Grants.gov

Once you have properly completed all required documents and attached any required or optional documentation, click on the **Check Package for Errors** button to ensure that you have successfully completed all required data fields. If any of the required fields are not completed you will receive an error notice which will indicate where revision is needed within your package. Correct any errors or if none are found, save the application package. The **Save & Submit** button will now become active and clicking this button will begin the application submission process. Only after the package has been saved with no errors will the **Save & Submit** button become active. The application package must then be saved once more before the submission process begins. Only an AOR will be able to perform the submit action, and they will be taken to the applicant login page to enter the Grants.gov username and password that was established in the Register with Grants.gov process (if not connected to the internet you will be instructed to do so).

4. Completing the SF424 Research and Related (R&R) Forms

4.1 Overview

This section contains all of the instructions you will need to complete the SF424 (R&R) forms.



Any agency-specific instructions are denoted by the DHHS logo displayed to the left of the paragraph, as illustrated here.

Conformance to all instructions is required and strictly enforced. Agencies may withdraw any applications from the review process that are not consistent with these instructions.

As you navigate through the forms, required fields are highlighted in yellow, outlined in red, and noted with an asterisk (*). Optional fields and completed fields are displayed in white. Data entered into a specific field is not accepted until you have navigated to the next field. If you enter invalid or incomplete information in a field, you will receive an error message.



Note the highlighted fields required for submissions, and the **Check Package for Errors** button, only refer to requirements and errors in the actual Adobe Reader forms. They do not refer to requirements or data errors against PHS business processes. Those validations will be performed by the eRA Commons system after the application has been submitted.

For those form components that are more than one page, click the **Next** button at the top of the form or scroll down (using the scroll bar on the right hand side of the screen) to navigate to a subsequent page. Once all data have been entered scroll up using the scroll bar to return to the Grant Application Package Screen.

4.2 Cover Component

OMB Number: 4040-0001 Expiration Date: 06/30/2011	
APPLICATION FOR FEDERAL ASSISTANCE SF 424 (R&R)	
1. * TYPE OF SUBMISSION <input type="checkbox"/> Pre-application <input type="checkbox"/> Application <input type="checkbox"/> Changed/Corrected Application	3. DATE RECEIVED BY STATE _____ State Application Identifier _____
2. DATE SUBMITTED _____ Applicant Identifier _____	4. a. Federal Identifier _____ b. Agency Routing Identifier _____
5. APPLICANT INFORMATION * Organizational DUNS: _____	
* Legal Name: _____ Department: _____ Division: _____ * Street1: _____ Street2: _____ * City: _____ County / Parish: _____ * State: _____ Province: _____ * Country: _____ USA: UNITED STATES * ZIP / Postal Code: _____	
Person to be contacted on matters involving this application Prefix: _____ * First Name: _____ Middle Name: _____ * Last Name: _____ Suffix: _____ * Phone Number: _____ Fax Number: _____ Email: _____	
6. * EMPLOYER IDENTIFICATION (EIN) or (TIN): _____	
7. * TYPE OF APPLICANT: _____ Please select one of the following Other (Specify): _____ Small Business Organization Type <input type="checkbox"/> Women Owned <input type="checkbox"/> Socially and Economically Disadvantaged	
8. * TYPE OF APPLICATION: <input type="checkbox"/> New <input type="checkbox"/> Resubmission <input type="checkbox"/> Renewal <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, mark appropriate box(es): <input type="checkbox"/> A. Increase Award <input type="checkbox"/> B. Decrease Award <input type="checkbox"/> C. Increase Duration <input type="checkbox"/> D. Decrease Duration <input type="checkbox"/> E. Other (specify): _____	
* Is this application being submitted to other agencies? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No What other Agencies? _____	
9. * NAME OF FEDERAL AGENCY: National Institutes of Health Stage	10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: _____ TITLE: _____
11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT: _____	
12. PROPOSED PROJECT: * Start Date _____ * Ending Date _____	* 13. CONGRESSIONAL DISTRICT OF APPLICANT _____
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION Prefix: _____ * First Name: _____ Middle Name: _____ * Last Name: _____ Suffix: _____ Position/Title: _____ * Organization Name: _____ Department: _____ Division: _____ * Street1: _____ Street2: _____ * City: _____ County / Parish: _____ * State: _____ Province: _____ * Country: _____ USA: UNITED STATES * ZIP / Postal Code: _____ * Phone Number: _____ Fax Number: _____ * Email: _____	

1. Type of Submission

Check one of the Type of Submission boxes. If this submission is to change or correct a previously submitted “New” application, click the **Changed/Corrected Application** box and enter the Grants.gov tracking number in the Federal Identifier field. If this submission is to change or correct a “resubmission,” “renewal” or “continuation” application, leave the Federal Identifier field as previously filled with the existing identifier (e.g., Award number). Do NOT insert the Grants.gov tracking number in these cases.

Unless requested by the agency, applicants may not use this to submit changes after the closing date. This field is required.



Pre-Application: Unless specifically noted in a program announcement, the Pre-application option is not used by NIH and AHRQ.

Changed/Corrected Application: This box must be used if you need to submit the same application again because of corrections for system validation errors or if a portion of the application was lost or distorted during the submission process. This option is for correcting system validation errors only and may not be used to include last minute changes to any of the PDF attachments. When submitting a Changed/Corrected Application:

- If submitting after the submission date, include an explanation in the Cover Letter Component. Note that if you are submitting additional grant application materials after the submission date some special guidelines may apply. See NIH Guide Notice NOT-OD-08-082 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-082.html>) for the NIH Policy on Submission of Additional Grant Application Materials.
- When you check the Changed/Correct Application box, Item 4. Federal Identifier becomes a required field.
- When submitting a Changed/Corrected Application for a “New” Type of Application (Item 8 = New), in the Federal Identifier field (Item 4)) enter the Grants.gov tracking number for the previous application that you are correcting. If you are unable to recall the Grants.gov tracking number, enter “N/A.”
- When submitting a Changed/Corrected Application for a “Resubmission” or “Renewal” Type of Application (Item 8 = Resubmission or Renewal), in the Federal Identifier field (Item 4) enter the IC and serial number of the previously assigned application/award number (e.g., CA987654).
- Do **not** use the Changed/Corrected Application box to denote a submission of a resubmission or amended application. That will be indicated in item 8. Type of Application.

2. Date Submitted and Applicant Identifier

Enter the date the application is submitted to Federal agency (or State if applicable). In the applicant identifier field enter the applicant’s control number (if applicable).



Note the Applicant Identifier field is a control number created by the applicant organization, not the Federal agency.

3. Date Received by State and State Application Identifier

Enter the date received by state (if applicable). In the State Application Identifier field, enter the state application identifier, if applicable.



For submissions to NIH and AHRQ, leave these fields blank.

4.a. Federal Identifier

New project applications should leave this field blank unless you are submitting a Changed/Corrected application or a New application following a Pre-Application. When submitting a changed/corrected “New” application, enter the Grants.gov tracking number. When a New Application is being submitted following a Pre-Application, enter the agency-assigned pre-application number, if applicable. If this is a continuation, revision, or renewal application, enter the assigned Federal Identifier number (for example, award number)--even if submitting a changed/corrected application.



For submissions to NIH and AHRQ, include only the IC and serial number of the previously assigned application/award number (e.g., CA987654).

Existing definitions for NIH and other PHS agencies applications are somewhat different:

- New is the same; i.e., an application that is submitted for the first time. See also the policy [Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code](#).
- Resubmission is equivalent to NIH and other PHS agencies Revision; i.e., a revised or amended application. See also the [NIH Policy on Resubmission Applications](#).
- Renewal is equivalent to NIH and other PHS agencies Competing Continuation, and is very rare for fellowship programs.
- Continuation is equivalent to NIH and other PHS agencies Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will **not** be used.
- Revision is somewhat equivalent to NIH and other PHS agencies Competing Supplement. Applicants should contact the awarding agency for advice on submitting any revision/supplement application. Revisions generally do not apply to individual fellowships.

Applicants to NIH and other PHS agencies should complete this field when submitting a resubmission, renewal or revision application. When submitting a “New” application, this field should remain blank unless you are submitting a Changed/Corrected Application. In this case, where Item 1 = Changed/Corrected Application and Item 8 = New, the Federal Identifier field becomes a required field. Therefore you must enter the Grants.gov tracking number assigned to the application that you are correcting. If you are unable to recall the tracking number, enter “N/A.”


4.b. Agency Routing Identifier

Enter the agency-assigned routing identifier per the agency-specific instructions.

5. Applicant Information





This information is for the Sponsoring Organization, not a specific individual. All references to “applicant organization” for individual fellowships refer to the Sponsoring Organization.

Field Name	Instructions
Organizational DUNS	<p>Enter the DUNS or DUNS+4 number of the applicant organization. This field is required.</p>  <p>For submission to NIH and AHRQ, this DUNS must match the number entered in the eRA Commons Institutional Profile for the applicant organization. The AOR is encouraged to confirm that a DUNS has been entered in the eRA Commons Institutional Profile prior to submitting an application. If your organization does not already have a DUNS number, you will need to go to the Dun & Bradstreet Web site at http://fedgov.dnb.com/webform to obtain the number.</p>
Legal Name	Enter the legal name of the applicant which will undertake the assistance activity, enter the complete address of the applicant (including county/parish and country), and name, telephone number, e-mail, and fax of the person to contact on matters related to this application.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization that will undertake the assistance activity.
Division	Enter the name of the primary organizational division, office, or major subdivision which will undertake the assistance activity.
Street1	Enter the first line of the street address for the applicant in “Street1” field. This field is required.
Street2	Enter the second line of the street address for the applicant in “Street2” field. This field is optional.
City	Enter the city for address of applicant. This field is required.
County/Parish	Enter the county or parish for address of applicant.
State	Enter the State where the applicant is located. This field is required if the applicant is located in the United States.
Province	Enter the Province.
Country	Select the country for the applicant address. This field is required.
ZIP Code	Enter the nine-digit Postal Code (e.g., ZIP code) of applicant. This field is required if the applicant is located in the United States. This field is required if a State is selected; optional for Province.

Person to be contacted on matters involving this application:



This information is for the Administrative or Business Official, not the Fellowship applicant. This person is the individual to be notified if additional information is needed and/or if an award is made. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the AO profile information contained in the eRA Commons.

Field Name	Instructions
Prefix	Enter the prefix (e.g., Mr., Mrs., Rev.) for the person to contact on matters related to this application.  See also the PHS Fellowship Supplemental Form for additional required contact information.
First Name	Enter the first (given) name of the person to contact on matters related to this application. This field is required.
Middle Name	Enter the middle name of the person to contact on matters related to this application.
Last Name	Enter the last (family) name of the person to contact on matters related to this application. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters related to this application.
Phone Number	Enter the daytime phone number for the person to contact on matters related to this application. This field is required.
Fax Number	Enter the fax number for the person to contact on matters related to this application.
Email	Enter the email address for the person to contact on matters related to this application.  Provide only one email address. This is a required field for applications submitted to NIH and AHRQ.

6. Employer Identification

Enter either TIN or EIN as assigned by the Internal Revenue Service. If your organization is not in the US, enter 44-4444444. This field is required.




If you have a 12-digit EIN established for grant awards from NIH or other PHS agencies, **enter all 12 digits (e.g., 1123456789A1).**


7. Type of Applicant





This information is for the Applicant Organization, not a specific individual AOR or PD/PI.

Field Name	Instructions
Type of Applicant	Select from the menu or enter the appropriate letter in the space provided.  Refer to FOA for eligible applicant information.
Other (Specify)	Complete only if “Other” is selected as the Type of Applicant.
Woman Owned	Check if you are a woman-owned small business – a small business that is at least 51% owned by a woman or women, who also control and operate it.
Socially and Economically Disadvantaged	Check if you are a socially and economically disadvantaged small business, as determined by the US Small Business Administration pursuant to Section 8(a) of the Small Business Act U.S.C. 637(a).

8. Type of Application

Field Name	Instructions
Type of Application	Select the type from the following list. Check only one. This field is required. <ul style="list-style-type: none"> • New: An application that is being submitted to an agency for the first time. • Resubmission: An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. • Renewal: An application requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as though the applicant is applying for the first time. Very rare for fellowships. • Continuation: A non-competing application for an additional funding/budget period within a previously approved project period. • Revision: An application that proposes a change in <ol style="list-style-type: none"> 1) the Federal Government’s financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award.  Note: Revisions are generally not applicable to fellowship applications. Existing definitions for NIH and other PHS agencies Type of Application are somewhat different: <ul style="list-style-type: none"> • New is the same. Check this option when submitting an

Field Name	Instructions
	<p>application for the first time. See also the policy Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code.</p> <ul style="list-style-type: none"> • Resubmission is equivalent to NIH and other PHS agencies Revision. Check this option when submitting a revised or amended application. See also the NIH Policy on Resubmission Applications. • Renewal is equivalent to NIH and other PHS agencies Competing Continuation and is very rare for fellowship programs. • Continuation is equivalent to NIH and other PHS agencies Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will not be used and should not be checked. • Revision is somewhat equivalent to NIH and other PHS agencies Supplement, but would also include other changes as noted in the definition above. In general, changes to the “terms and conditions of the existing award” (as noted in example 2 above) would not require the submission of another application through Grants.gov. Applicants should contact the awarding agency for advice on submitting any revision/supplement application. It is important to note that revisions for Fellowship applications are very rarely allowed. <p>This field also affects how you complete Item 4. Federal Identifier. If “Type of Application” is “New”, you can leave the Federal Identifier field blank on the first submission attempt. However, the Federal Identifier field becomes a required field when submitting a Changed/Corrected application to address errors/warnings. When submitting a Changed/Corrected “New” application, enter the Grants.gov tracking number of the previous submission attempt (e.g. GRANT87654321). If you are unable to find the tracking number, enter “N/A”.</p> <p>If “Type of Application” is “Renewal” or “Resubmission,” enter the IC and serial number of the previously assigned application/award number (e.g. CA987654). For these types of applications, do not change the Federal Identifier field when submitting Changed/Corrected applications.</p>
If Revision, mark appropriate box(es)	 <p>Generally not applicable to fellowships. Leave blank.</p>
Other	If “Other” is selected for Revision, add text to explain.

Field Name	Instructions
Is this application being submitted to other agencies?	<p>Check applicable box. This field is required.</p>  <p>In the field “Is this application being submitted to other agencies?,” please check the box “yes” if one or more of the specific aims submitted in your application are also contained in a similar, identical, or essentially identical application submitted to another Federal agency. Indicate the agency or agencies to which the application has been submitted. For additional information, please see NIH Guide Notice NOT-OD-09-100, <i>Reminder and Clarification of NIH Policies on Similar, Identical, or Essentially Identical Applications, Submission of Applications Following RFA Review, and Submission of Applications with a Changed Activity Code</i>, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html.</p>
What Other Agencies?	Enter Agency name.

9. Name of Federal Agency

Name the Federal agency from which assistance is being requested with this application. This information is pre-populated by Grants.gov.

10. Catalog of Federal Domestic Assistance (CFDA) Number and Title (CFDA)

Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested. This information is pre-populated by Grants.gov.



This field may be blank if you are applying to an opportunity that references multiple CFDA numbers. When this field is blank, leave it blank; the field will not allow any data entry. The appropriate CFDA number will be automatically assigned by the agency once the application is assigned to the appropriate awarding component.

11. Descriptive Title of Applicant’s Project

Enter a brief descriptive title of the project. This field is required.



A “new” application must have a different title from any other PHS project with the same Fellowship applicant. A “resubmission” or “renewal” 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.

NIH and other PHS agencies limit title character length to 81 characters, including the spaces between words and punctuation. Titles in excess of 81 characters will be truncated. Be sure to only use standard characters in the descriptive title: A through Z, a through z, 0 through 9, and underscore (_).

12. Proposed Project

Start Date: Enter the proposed start date of the project. This field is required.

Ending Date: Enter the proposed ending date of the project. This field is required.

13. Congressional District of Applicant

Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California’s 5th district, CA-012 for California’s 12th district.

If outside the U.S., enter 00-0000.

To locate your congressional district, visit the Grants.gov web site.




For States and U.S. territories with only a single congressional district enter “001” for the district code. For jurisdictions with no representative, enter “099”. For jurisdictions with a nonvoting delegate, enter “098” for the district number. Example: DC-098, PR-098.

14. Program Director/Principal Investigator (PD/PI) Contact Information



The PD/PI is the applicant for the Fellowship.




Field Name	Instructions
Prefix	The Project Director/Principal Investigator (PD/PI) is the individual responsible for the overall scientific and technical direction of the project. Enter the prefix of the PD/PI.
First Name	Enter the first name of the PD/PI. This field is required.
Middle Name	Enter the middle name of the PD/PI.
Last Name	Enter the last name of the PD/PI. This field is required.
Suffix	Enter the suffix of the PD/PI.  Do not use this field to record degrees. Degrees for the PD/PI are requested separately in the PHS Fellowship Cover Page Supplement.
Position/Title	Enter the Position/Title of the PD/PI.
Organization Name	Enter the organization name of the PD/PI.
Department	Enter the department of the PD/PI.
Division	Enter the division of the PD/PI.
Street1	Enter first line of the street address for the PD/PI in the “Street1” field. This field is required.
Street2	Enter the second line of the street address for the PD/PI in the “Street2” field. This field is optional.
City	Enter the City for address of the PD/PI. This field is required.
County/Parish	Enter the county or parish for address of the PD/PI.

Field Name	Instructions
State	Enter the State where the PD/PI is located. This field is required if the PD/PI is located in the United States.
Province	Enter the province for PD/PI.
Country	Select the country for the PD/PI address.
ZIP/Postal Code	Enter the nine-digit Postal Code (e.g., ZIP Code) of the PD/PI. This field is required if the PD/PI is located in the United States.
Phone Number	Enter the daytime phone number for the PD/PI. This field is required.
Fax Number	Enter the fax number for the PD/PI.
Email	Enter the email address for the PD/PI. This field is required.

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15. ESTIMATED PROJECT FUNDING a. Total Federal Funds Requested <input style="width: 100%;" type="text"/> b. Total Non-Federal Funds <input style="width: 100%;" type="text"/> c. Total Federal & Non-Federal Funds <input style="width: 100%;" type="text"/> d. Estimated Program Income <input style="width: 100%;" type="text"/>	16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS? a. YES <input type="checkbox"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE: <input style="width: 100%;" type="text"/> b. NO <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372; OR <input type="checkbox"/> PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW	
17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001) <input checked="" type="checkbox"/> * I agree <small>* The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.</small>		
18. SFLLL or other Explanatory Documentation <input style="width: 100%;" type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>		
19. Authorized Representative Prefix: <input style="width: 100%;" type="text"/> * First Name: <input style="width: 100%;" type="text"/> Middle Name: <input style="width: 100%;" type="text"/> * Last Name: <input style="width: 100%;" type="text"/> Suffix: <input style="width: 100%;" type="text"/> * Position/Title: <input style="width: 100%;" type="text"/> * Organization: <input style="width: 100%;" type="text"/> Department: <input style="width: 100%;" type="text"/> Division: <input style="width: 100%;" type="text"/> * Street1: <input style="width: 100%;" type="text"/> Street2: <input style="width: 100%;" type="text"/> * City: <input style="width: 100%;" type="text"/> County / Parish: <input style="width: 100%;" type="text"/> * State: <input style="width: 100%;" type="text"/> Province: <input style="width: 100%;" type="text"/> * Country: <input style="width: 100%;" type="text"/> USA: UNITED STATES * ZIP / Postal Code: <input style="width: 100%;" type="text"/> * Phone Number: <input style="width: 100%;" type="text"/> Fax Number: <input style="width: 100%;" type="text"/> * Email: <input style="width: 100%;" type="text"/> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> * Signature of Authorized Representative <input style="width: 100%;" type="text"/> Completed on submission to Grants.gov </div> <div style="width: 45%;"> * Date Signed <input style="width: 100%;" type="text"/> Completed on submission to Grants.gov </div> </div>		
20. Pre-application <input style="width: 100%;" type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>		

15. Estimated Project Funding

Field Name	Instructions
a. Total Federal Funds Requested	<p>Enter total Federal funds requested for the entire project period. This field is required.</p>  <p>Applicants should refer to the NIH/OER Research Web site (http://grants.nih.gov/training/extramural.htm) for current stipend and other budgetary levels, and enter the total amount being requested for the entire period of support. This amount includes the applicable stipend amount, the actual tuition and fees, and the standard institutional allowance.</p> <p>For non-NRSA programs, applicants should refer to the specific FOA for budget information.</p>
b. Total Non-Federal Funds	<p>Enter total non-Federal funds proposed for the entire project period.</p>
c. Total Federal & Non-Federal Funds	<p>Enter total estimated funds for the entire project period, including both Federal and non-Federal funds. This is required information.</p>  <p>For NIH and AHRQ applicants, this field will be the same as the item 15a unless the specific announcement indicates that cost sharing is a requirement.</p>
d. Estimated Program Income	<p>Identify any Program Income estimated for this project period if applicable. This field is required.</p>  <p>Not applicable to fellowships. Enter \$0.00.</p>

16. Is Application Subject to Review by State Executive Order 12372 Process?

If yes, check box. If the announcement indicates that the program is covered under Executive Order 12372, applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372. If no, check appropriate box.

If block 16a is checked, insert date application was submitted to State.



For NIH and other PHS agencies submissions using the SF424 (R&R), applicants should check “No, Program is not covered by E.O. 12372.”

17. Certification

Check “I agree” to provide the required certifications and assurances. This field is required.



The list of NIH and other PHS agencies Assurances, Certifications, and other Policies is found in [Part III, Policies, Assurances, Definitions, and Other Information](#).

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.

18. SFLLL or Other Explanatory Documentation

If applicable, attach the SFLLL or other explanatory document per agency instructions.



If unable to certify compliance in Item 17 (above), attach an explanation. Additionally, as applicable, attach the SFLLL (Standard Form LLL, Disclosure of Lobbying Activities) or other documents in this item. A fillable version of the SFLLL form is available at <http://www.whitehouse.gov/omb/assets/omb/grants/sflllin.pdf>.

19. Authorized Representative



This is equivalent to the individual with the organizational authority to sign for an application; otherwise known as the Authorized Organizational Representative or the Signing Official.

Field Name	Instructions
Prefix	Enter the prefix (Mr., Mrs., Rev.) for the name of the Authorized Representative.
First Name	Enter the first (given) name of the Authorized Representative. This field is required.
Middle Name	Enter the middle name of the Authorized Representative.
Last Name	Enter the last (family) name of the Authorized Representative. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the name of the Authorized Representative.
Position/Title	Enter the title of the Authorized Representative. This field is required.
Organization	Enter the name of the organization for the Authorized Representative. This field is required.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the Authorized Representative.
Division	Enter the name of the primary organizational division, office, or major subdivision of the Authorized Representative.
Street1	Enter the first line of the street address for the Authorized Representative in the "Street1" field. This field is required.
Street2	Enter the second line of the street address for the Authorized Representative in the "Street2" field. This field is optional.
City	City for address of the Authorized Representative. This field is required.

Field Name	Instructions
County/Parish	Enter the county or parish for address of the Authorized Representative.
State	Enter the state where the Authorized Representative is located. This field is required if the Authorized Representative is located in the United States.
Province	Enter the province for the Authorized Representative.
Country	Select the country for the Authorized Representative address.
ZIP/Postal Code	Enter the nine-digit postal code (e.g., ZIP code) of the Authorized Representative. This field is required if the Authorized Representative is located in the United States.
Phone Number	Enter the daytime phone number for the Authorized Representative. This field is required.
Fax Number	Enter the fax number for the Authorized Representative.
Email	Enter the email address for the Authorized Representative. This field is required.
Signature of Authorized Representative	It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application to Grants.gov. If this application is submitted through Grants.gov, leave blank. If a hard copy is submitted, the AOR must sign this block.
Date Signed	If this application is submitted through Grants.gov, the system will generate this date. If submitting a hard copy, enter the date the AOR signed the application.

20. Pre-Application

If you are submitting a pre-application, provide a summary description of the project in accordance with the announcement and/or agency specific instructions, and save the file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.



Unless specifically noted in a program announcement, NIH and other PHS agencies do not use *Pre-applications*.

Not applicable for NIH and AHRQ Fellowships. Leave blank.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

4.3 Project/Performance Site Locations Component

OMB Number: 4040-0010
Expiration Date: 08/31/2011

Project/Performance Site Location(s)

Project/Performance Site Primary Location I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Project/Performance Site Location 1 I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Additional Location(s)

Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other site(s), identify the site location(s) in the blocks provided.



Project/Performance Site Primary Location

One of the sites indicated must be the sponsoring organization; generally, the Primary Location should be that of the sponsoring organization. Indicate where the training described in the Research Training Plan will be conducted. If there is more than one training site, including any Department of Veterans Affairs (VA) facilities and foreign sites, list them all in the fields provided for Location 1 - # below.

If there are unusual circumstances involved in the research training proposed, such as fieldwork or a degree sought from an institution other than the one in which the research training will take place, describe these circumstances in Item 10, Facilities and Resources of the Other Project Information form.

Unless otherwise instructed in a FOA, do **not** check the box indicating “I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.”


If a training site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the site operates under and 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 Part II of this Application Guide and in the NIH Grants Policy Statement.

For research involving live vertebrate animals, the applicant organization must ensure that training 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.

Foreign Sponsorship

An individual may request support for training abroad. In such cases, the applicant is required to provide detailed justification for the foreign training, including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Foreign training will be considered for funding only when the scientific advantages are clear. The foreign justification should be provided as a separate attachment in Item 12. Other Attachments in the Other Project Information Component.

Field Name	Instructions
Organization Name	Indicate the organization name of the primary site where the work will be performed.
DUNS Number	Enter the DUNS number associated with the organization where the project will be performed.
Street1	Enter first line of the street address of the primary performance site location. This field is required.
Street2	Enter second line of the street address of the primary performance site location, if applicable.
City	Enter the city for address of the primary performance site location. This field is required.
County/Parish	Enter the county or parish of the primary performance site location.

Field Name	Instructions
State	Select the state of the primary performance site location. This field is not active until USA has been selected for the country. This field is required if the performance site location is in the United States.
Province	Enter the province of the primary performance site location.
Country	Select the country of the primary performance site location. This field is required.
ZIP Code	Enter the nine-digit postal code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States.
Project/Performance Site Congressional District	<p>Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California’s 5th district, CA-012 for California’s 12th district.</p> <p>If all districts in a state are affected, enter “all” for the district number. Example MD-all for all congressional districts in Maryland.</p> <p>If nationwide (all districts in all states), enter US-all.</p> <p>If the program/project is outside the US, enter 00-0000.</p> <p>To locate your congressional district, visit the Grants.gov web site. Note it is likely this field will be identical to the “Congressional District of Applicant” field provided elsewhere in the application.</p> <p> For States and U.S. territories with only a single congressional district enter “001” for the district code. For jurisdictions with no representative, enter “099”. For jurisdictions with a nonvoting delegate, enter “098” for the district number. Example: DC-098, PR-098.</p>

Project/Performance Site Location 1

Field Name	Instructions
Organization Name	Enter the name of organization of the performance site location.
DUNS Number	Enter the DUNS number associated with the organization where the project will be performed.
Street1	Enter first line of the street address of the performance site location. This field is required.
Street2	Enter second line of the street address of the performance site location, if applicable.
City	Enter the city of the performance site location. This field is required.

Field Name	Instructions
County/Parish	Enter the county or parish of the performance site location.
State	Select the state where the performance site is located. This field is not active until USA has been selected for the country. This field is required if the performance site location is in the United States.
Province	Enter the province of the performance site location.
Country	Select the country for the performance site location. This field is required.
ZIP Code	Enter the nine-digit postal code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States.
Project/Performance Site Congressional District	<p>Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California’s 5th district, CA-012 for California’s 12th district.</p> <p>If all districts in a state are affected, enter “all” for the district number. Example MD-all for all congressional districts in Maryland.</p> <p>If nationwide (all districts in all states), enter US-all.</p> <p>If the program/project is outside the US, enter 00-0000.</p> <p>To locate your congressional district, visit the Grants.gov web site. Note it is likely this field will be identical to the “Congressional District of Applicant” field provided elsewhere in the application.</p> <p>For States and U.S. territories with only a single congressional district enter “001” for the district code. For jurisdictions with no representative, enter “099”. For jurisdictions with a nonvoting delegate, enter “098” for the district number. Example: DC-098, PR-098.</p>

For additional performance site locations, click **Next Site** to display the fields for Project/Performance Site Locations 3 through 30.

If you need to add more than thirty locations, enter the information in a separate file. In the Additional Locations section at the bottom of the form, click **Add Attachment**, select the file, and then click **Open**. A sample Additional Performance Sites format page for greater than eight locations is found under “Additional Format Pages” at: <http://grants.nih.gov/grants/funding/424/index.htm>.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

4.4 Other Project Information Component

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? Yes No

1.a If YES to Human Subjects

Is the Project Exempt from Federal regulations? Yes No

If yes, check appropriate exemption number. 1 2 3 4 5 6

If no, is the IRB review Pending? Yes No

IRB Approval Date:

Human Subject Assurance Number:

2. * Are Vertebrate Animals Used? Yes No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? Yes No

IACUC Approval Date:

Animal Welfare Assurance Number

3. * Is proprietary/privileged information included in the application? Yes No

4.a. * Does this project have an actual or potential impact on the environment? Yes No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? Yes No

4.d. If yes, please explain:

5. * Is the research performance site designated, or eligible to be designated, as a historic place? Yes No

5.a. If yes, please explain:

6. * Does this project involve activities outside of the United States or partnerships with international collaborators? Yes No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. * Project Summary/Abstract

8. * Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments

NOTE: Component 4.4 should be completed in consultation with the Sponsor and Administrative Officials at the Sponsoring Institution.

1. Are Human Subjects Involved?

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time during the proposed project at any performance site, select no and skip the rest of block 1. This field is required.



Check “Yes” if use of human subjects is “Indefinite.” If the sponsoring institution has an approved FWA on file with OHRP, but at the time of application, plans for the involvement of human subjects are so indefinite that IRB review and approval are not feasible, check “Yes.” If

the award is made, human subjects research may not commence until a verification of IRB approval has been submitted to the NIH IC or AHRQ. See also [PHS Fellowship Supplemental Form \(Section 5.3\)](#) for a specific data item on “Indefinite Human Subjects Involvement.”

Applications proposing human subjects research may be required to submit additional information, forms, or attachments with the application, in accordance with NIH and AHRQ policies covering human subjects research. Refer to [Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan](#).

1.a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? Yes/No

Yes: If the project is exempt from Federal regulations, check Yes.

No: If the project is not exempt from Federal regulations, check No.

If yes, check appropriate exemption number 1, 2, 3, 4, 5, 6

Select the appropriate exemption number from 1, 2, 3, 4, 5, 6.

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.



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/policy/exempt_res_det.html#FAQ1). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated 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.

If no, is the IRB review Pending? Yes/No

If IRB review is pending, check Yes. If IRB review is not pending, check No.

IRB Approval Date

Enter the latest Institutional Review Board (IRB) approval date (if available). Leave blank if Pending.



Applicants should check “Yes” to the question “Is the IRB review Pending?” even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle as a [Just-In-Time](#) requirement.

Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number. Do not enter the FWA before the number.



Insert “None” if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature in item 19 on the SF424 (R&R)

Cover component, is declaring that it will comply with 45CFR Part 46 and proceed to obtain a human subjects assurances (see <http://www.hhs.gov/ohrp>). **Do not insert the human subjects assurance number of any collaborating institution in the space provided.**

Note: For a temporary period during the transition to this new form set, this field is no longer available if Yes is checked to *If no, is the IRB review Pending?* Applicants in this situation should instead be prepared to provide this information in the eRA Commons as part of the Just-in-Time process (see [Part III, Section 1.7](#) for more information).

In many instances, the applicant (Fellowship applicant) will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption has been designated. This review or exemption designation is sufficient, provided that the IRB determines that participation of the applicant does not substantially modify the research.

If the sponsoring institution has an approved FWA or MPA on file with OHRP that covers the specific activity, provide the number and the latest date of approval by the IRB of the proposed activities. This date must be no earlier than one year before the receipt date for which the application is submitted.

2. Are Vertebrate Animals Used?

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2.



Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

Also check “Yes” if use of animals is “Indefinite.” If the sponsoring institution has an approved Animal Welfare Assurance on file with OLAW but, at the time of application, plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, check “Yes”. If an award is made, vertebrate animals may not be involved until a verification of the date of IACUC approval has been submitted to the NIH IC or AHRQ. See the [PHS Fellowship Supplemental Form \(Section 5.3\)](#) for a specific data item on “Indefinite Vertebrate Animal Use.”

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?

Indicate if an Institutional Animal Care and Use Committee (IACUC) review is pending.

Yes: Indicate if an Institutional Animal Care and Use Committee (IACUC) review is pending.

No: Indicate if an Institutional Animal Care and User Committee (IACUC) review is pending. Click **No**, if no review is pending.

IACUC Approval Date

Enter the latest IACUC approval date (if available). Leave blank if Pending.

Animal Welfare Assurance Number

Enter the Federally approved assurance number, if available.



To determine if your organization holds an Animal Welfare Assurance, see <http://grants.nih.gov/grants/olaw/olaw.htm#assur>. Applicants should check “Yes” to the question “Is the IACUC review Pending?” even if the IACUC review/approval process has not yet begun at the time of submission. Also note that an IACUC Approval Date is not required at the time of submission. However, the approval date and other data may be requested later in the pre-award cycle as a Just-In-Time requirement. If the applicant organization does not have an approved Animal Welfare Assurance on file with the [Office of Laboratory Animal Welfare \(OLAW\), NIH](#), enter “None” in the Animal Welfare Assurance Number field. **Do not enter the Animal Welfare**

Assurance number of any collaborating institution. By inserting “None” at the time of submission, the applicant organization is essentially declaring that it will comply with the [PHS Policy on Humane Care and Use of Laboratory Animals](#) by submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OLAW.

In many instances, the Fellow will be participating in research supported by research project grants for which the IACUC review has been obtained. This review is sufficient, provided that participation of the Fellow does not substantially modify the research. The appropriate grant(s) must be identified along with the IACUC approval date(s).

The Sponsoring Institution must ensure that the Fellow is enrolled in the institution’s animal welfare training and safety programs for personnel who have contact with animals, as appropriate. It is also the Sponsoring Institution’s responsibility to ensure that the Fellow is properly supervised when working with live vertebrate animals.

Also see PHS Fellowship Supplemental Form for additional information ([Section 5.3](#)).

3. Is proprietary/privileged information included in the application?

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation." This field is required.

4. Environmental Questions



Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer ‘No’ to this question unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the box marked “Yes” should be checked and an explanation provided in field 4.b.

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous waste, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.

9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

4.a. Does this project have an actual or potential impact on the environment?

Indicate if this project has an actual or potential impact on the environment? Click **No** here if this is not the case. This field is required.

4.b. If yes, please explain

Explanation of the actual or potential impact on the environment.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? - Check yes or no.

4.d. If yes, please explain

Enter additional details about the EA or EIS. If desired, you can provide the information in a separate file, and attach by clicking **Add Attachments** located to the right of Item 12 - Other Attachments.

5. Is the research performance site designated, or eligible to be designated, as a historic place? Yes/No

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes box and then provide an explanation in the box provided in 5.a. Otherwise, check the No box. This field is required.

5.a. If yes, please explain:

If you checked the Yes box indicating any performance site is designated, or eligible to be designated, as a historic place, provide the explanation here.

6. Does this project involve activities outside of the United States or partnerships with International Collaborators?

Indicate whether this project involve activities outside of the United States or partnerships with international collaborators. Check yes or no. This field is required.



Applicants to NIH and AHRQ must check “Yes” if the applicant organization is a foreign institution or if the project includes a foreign component. For a definition of a [foreign component](#), see “Definitions” section of Part III: Policies, Assurances, Definitions, and Other Information.

6.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.

6.b. Optional Explanation

Enter an explanation for involvement with outside entities (optional). If desired, you can provide the information in a separate file, and attach by clicking **Add Attachments** located to the right of Item 12, Other Attachments.



If you have checked “Yes” to 6, applicants to the NIH and AHRQ must describe special resources or characteristics of the research training project including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training experience as compared to the training available domestically. Provide this information in a separate file, attaching it as Item 12, Other Attachments. In the body of the text, begin the section

with a heading indicating “Foreign Justification.” When saving this file, please name it “Foreign Justification” as well.

7. Project Summary/Abstract

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information. Please click the **Add Attachment** button to the right of this field to complete this entry.



The first and major component of the Project Summary/Abstract (i. e., “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 training program design and methods 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. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text, and follow the required [font and margin specifications](#). An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

As noted above, 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 and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at <http://report.nih.gov>) and will become public information.

The attachment must be in PDF format. (See [Section 2.6](#) for additional information on preparing attachments.)

8. Project Narrative

Provide Project Narrative in accordance with the announcement and/or agency-specific instructions. Please click the **Add Attachment** button to the right of this field to complete this entry.



For NIH and other PHS agencies applications, this attachment will reflect the second component of the Project Summary. The second component of the Project Summary/Abstract (i.e., “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.

A separate Research Training Plan component is required for NIH and AHRQ applications. Refer to Section 5.3, PHS Fellowship Supplemental Form, B, numbers 2 and 3 for separate file uploads and instructions.

9. Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the 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. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application. To attach a document for Bibliography and References Cited, click **Add Attachment**.



Unless otherwise noted in an FOA, this section is required for submissions to NIH and AHRQ. This section (formerly “Literature Cited”) should include any references cited in the PHS Fellowship Research Training Plan component (see [Section 5.3](#) for details on completing that component). 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.

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). 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.

10. Facilities & Other Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. Please click the **Add Attachment** button to the right of this field to complete this entry.



No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). 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 will employ useful collaborative arrangements.

If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Training Plan, Item 15 (Select Agent Research).

11. Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Please click the **Add Attachment** button to the right of this field to complete this entry.

12. Other Attachments

Attach a file to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction.



A. Required Attachments

1. List of Referees

All fellowship applicants must include a list of References here. This same list must also be provided in the Cover Letter Component. The list must include the names, degrees, and affiliations of the individuals from whom you have asked to submit reference letters.

At least three references are required. Your references should be carefully selected. Only those individuals who can make the most meaningful comments about your qualifications for a research career should be used. *The sponsor of this application cannot be counted as a reference. The sponsor's recommendation is included as part of the application (See Sponsor/Co-Sponsor Information).* Whenever possible, select at least one referee who is not in your current department. If not submitting a reference from the dissertation advisor or chief of service, provide an explanation.

For postdoctoral applications, references from graduate or medical school are preferred over those from undergraduate school.

Request reference reports only from individuals who will be able to submit them in time. See [Section 5.4](#) for additional information and instructions for referees. Consider any factor (e.g., illness or extended vacation) that might cause an inordinate delay. Give these reference forms to the referees well in advance of the application submission date.

Failure to provide references may delay processing of your application or may result in the application being returned to you without review.

2. Sponsor and any Co-Sponsor(s) (if any) Information (Limit to 6 pages)

Create a heading at the top of the first page titled "Section II--Sponsor and Co-Sponsor Information."

Complete these items as comprehensively as possible so that a meaningful evaluation of the training environment can be made by the reviewers.

a. Research Support Available

In a table, list all current and pending research and research training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, and name of the principal investigator, dates, and amount of the award. Include this information for any co-sponsor as well.

b. Sponsor's/Co-Sponsor's Previous Fellows/Trainees

Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select five that are representative and, for those five, provide their present employing organizations and position titles or occupations. Include this information for any co-sponsor as well.

c. Training Plan, Environment, Research Facilities

Describe the research training plan that you have developed specifically for the Fellowship applicant. Include items such as classes, seminars, and opportunities for interaction with other groups and scientists. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career goals. Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals.

d. Number of Fellows/Trainees to be Supervised During the Fellowship

Indicate whether pre- or postdoctoral. Include this information for any co-sponsor as well.

e. Applicant's Qualifications and Potential for a Research Career

Describe how the Fellowship applicant is suited for this research training opportunity based on his/her academic record and research experience level, including how the research training plan, and your own expertise as the sponsor will assist in producing an independent researcher.

B. Additional Attachments (When Applicable)

Some FOAs require additional documents or certifications that will need to be uploaded here for individual fellowship applications.

1. Collaborators and Dissertation Advisor(s), if applicable

Attachments may be provided (if applicable) by collaborators, consultants, advisors, etc. Relevant information applicable to the fellow's planned research training and future goals may be provided by any contributor or advisor via an attachment.

2. Certification Letter for Predoctoral Fellowships (F31) to Promote Diversity

Applications submitted for Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research are required to attach a Certification Letter (titled: Diversity_Eligibility_Ltr) from the institution certifying eligibility of the Fellowship applicant for the program. The Certification Letter must be on institutional letterhead and scanned so that an institutional official signature is visible.

Attach a file(s) to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction by clicking **Add Attachment**, browsing to where you saved the file, selecting the file, and then clicking **Open**.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

4.5 Senior/Key Person Profile (Expanded) Component

OMB Number: 4040-0001
 Expiration Date: 06/30/2011

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:
 * Last Name: Suffix:
 Position/Title: Department:
 Organization Name: Division:
 * Street1:
 Street2:
 * City: County/ Parish:
 * State: Province:
 * Country: USA: UNITED STATES * Zip / Postal Code:
 * Phone Number: Fax Number:
 * E-Mail:
 Credential, e.g., agency login:

* Project Role: Other Project Role Category:

Degree Type:
 Degree Year:

*Attach Biographical Sketch
 Attach Current & Pending Support

PROFILE - Senior/Key Person 1

Prefix: * First Name: Middle Name:
 * Last Name: Suffix:
 Position/Title: Department:
 Organization Name: Division:
 * Street1:
 Street2:
 * City: County/ Parish:
 * State: Province:
 * Country: USA: UNITED STATES * Zip / Postal Code:
 * Phone Number: Fax Number:
 * E-Mail:
 Credential, e.g., agency login:

* Project Role: Other Project Role Category:

Degree Type:
 Degree Year:

*Attach Biographical Sketch
 Attach Current & Pending Support



To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.


This section will be unnecessary for the majority of fellowship applications. This component provides the ability to collect structured data for up to 40 Senior/Key Persons. Data must be entered for the first 40 individuals (PD/PI + 39 others) before the Additional Senior/Key Person Form Attachments section becomes available. The information for the PD/PI continues to be pre-populated from the SF424 (R&R) Cover component. See instructions in [Section 4.2 Cover Component](#) if these fields are empty.

Starting with the PD/PI (Fellowship applicant), provide a profile for each Senior/Key Person proposed. Unless otherwise specified in an agency announcement, Senior/Key Personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.


Profile – Program Director/Principal Investigator (PD/PI) – Fellowship Applicant

Field Name	Instructions
Prefix	This field is automatically populated from the SF424 (R&R). It is the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	This field is automatically populated from the SF424 (R&R). It is the first (given) name of the PD/PI. This field is required.
Middle Name	This field is automatically populated from the SF424 (R&R). It is the middle name of the PD/PI.
Last Name	This field is automatically populated from the SF424 (R&R). It is the last (family) name of the PD/PI. This field is required.
Suffix	This field is automatically populated from the SF424 (R&R). It is the suffix (e.g., Jr., Sr., PhD) for the name of the PD/PI.
Position/Title	This field is automatically populated from the SF424 (R&R). It is the title of the PD/PI.
Department	This field is automatically populated from the SF424 (R&R). It is the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Organization Name	This field is automatically populated from the SF424 (R&R). It is the name of the organization of the PD/PI.
Division	This field is automatically populated from the SF424 (R&R). It is the name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	This field is automatically populated from the SF424 (R&R). It is the first line of the street address of the PD/PI. This field is required.
Street2	This field is automatically populated from the SF424 (R&R). It is the second line of the street address of the PD/PI, if applicable. This field is optional.

Field Name	Instructions
City	This field is automatically populated from the SF424 (R&R). It is the city for the address of the PD/PI.
County/Parish	This field is automatically populated from the SF424 (R&R). It is the county or parish for the address of the PD/PI.
State	This field is automatically populated from the SF424 (R&R). It is the state where the PD/PI is located. This field is required if the PD/PI is located in the United States.
Province	This field is automatically populated from the SF424 (R&R). It is the province where the PD/PI is located.
Country	This field is automatically populated from the SF424 (R&R). It is the country for the PD/PI address.
ZIP Code	This field is automatically populated from the SF424 (R&R). The nine-digit Postal Code (e.g., ZIP Code) of the PD/PI. This field is required if the PD/PI is located in the United States.
Phone Number	This field is automatically populated from the SF424 (R&R). It is the daytime phone number for the PD/PI. This field is required.
Fax Number	This field is automatically populated from the SF424 (R&R). It is the fax number for the PD/PI.
Email	This field is automatically populated from the SF424 (R&R). It is the email address for the PD/PI. This field is required for the PD/PI.
Credential, e.g., agency login	<p>If you are submitting to an agency (e.g., NIH) where you have an established personal profile, enter the agency ID. If not, leave blank.</p>  <p>For NIH and AHRQ, registration in the eRA Commons for all PD/PIs is required. The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.</p>
Project Role	<p>Select one. Use "Other" if a category is not listed in the pick list.</p>  <p>Select Program Director/Principal Investigator for the Fellowship applicant.</p>
Other Project Role Category	Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist.

Field Name	Instructions
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., RN). This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information.
Attach Biographical Sketch	<p>Provide a biographical sketch for the PD/PI (Fellowship Applicant). Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach. This is required information.</p> <p> For Fellowship applications, the PD/PI is the Fellowship applicant. Biographical sketches should follow the format described below.</p> <p>PD/PI (Fellowship applicant) Biographical Sketch (MS Word)</p> <p><i>The Fellowship Applicant Biographical Sketch Format Page is available only in MS Word format.</i></p> <p>The biographical sketch for you, the Fellowship applicant, is very similar to the traditional biographical sketch format used by your sponsor. However, there are notable differences so follow these special instructions and use the special sample format provided.</p> <p>If you are applying for a predoctoral or postdoctoral fellowship, use this custom biographical sketch format page.</p> <p>If you are applying for a Senior Fellowship, use the traditional Biographical Sketch Format Page.</p> <p>The Fellowship Applicant Biographical Sketch for all fellowship levels may not exceed four pages per person. This 4-page limit includes the table at the top of the first page. See a sample of a completed Biographical Sketch.</p> <p>Complete the information at the top of the form. Include the assigned eRA Commons User Name for the Fellowship applicant (PD/PI), as required in Part I, Section 2.2.2.2. This data item is the same as provided in the Credential field on the Senior/Key Person Profile form and is required for the Fellowship applicant.</p> <p>Education/Training</p> <p>List all degree programs beginning with baccalaureate or other initial professional education and licensure, such as nursing (RN). Include all dates (month (mm) and year (yyyy)) of degrees received or expected, in addition to other information requested.</p> <p>A. Personal Statement</p> <p>Briefly describe why your experience and qualifications make you particularly well-suited for your role as a Fellowship applicant.</p>

Field Name	Instructions
	<p>B. Positions and Honors</p> <p>List in chronological order all non-degree training, including postdoctoral research training, all employment after college, and any military service. Clinicians should include information on internship, residency and specialty board certification (actual and anticipated with dates) in addition to other information requested. This information is used in reviewing the application and in determining the stipend level for Postdoctoral Fellowships. State the Activity/Occupation and include beginning/end dates, field, name of institution/company, and the name of your supervisor/employer.</p> <p>List any academic and professional honors that would reflect upon your potential for a research career and qualifications for an Individual Fellowship. Include all scholarships, traineeships, fellowships, and development awards other than Kirschstein-NRSA. Indicate sources of awards, dates, and grant or award numbers. List current memberships in professional societies, if applicable.</p> <p>C. Publications</p> <p>List your entire bibliography, separating research papers, abstracts, book chapters, and reviews. Within each subsection the list should be chronological. <i>If the list of publications cannot be accommodated within the four-page biosketch limit, select only the most pertinent publications or limit the list to no more than 15 publications.</i> For each publication, list the authors in published sequence, full title of article, journal, volume number, page numbers, and year of publication. Indicate if you previously used another name that is reflected in any of the citations. URLs or NIH PubMed Central (PMC) submission identification numbers may be included along with the full reference. While there is no limit to the number of URLs or PMC submission identification numbers that can be cited, applicants should be both judicious and concise. Manuscripts listed as “pending publication” or “in preparation” should be included and identified.</p> <p>D. Scholastic Performance</p> <p>Predoctoral applicants: Using the chart provided, list by institution and year all undergraduate and graduate courses with grades.</p> <p>In addition, in the space following the chart, explain any marking system if other than 1-100, A, B, C, D, F, or 0-4.0 if applicable. Show levels required for a passing grade. At the bottom of the page, Predoctoral applicants must also type in their scores for the Graduate Record Examination (GRE), if available; and M.D./Ph.D. applicants should type in their MCAT scores, if available.</p> <p>Postdoctoral applicants: Using the chart provided, list by institution and year all undergraduate courses and graduate scientific and/or professional courses germane to the training sought under this award with grades. In the space following the chart, explain any marking system if other than 1-100, A, B, C, D, F, or 0-4.0 if applicable. Show</p>

Field Name	Instructions
	<p>levels required for a passing grade.</p> <p>Predoctoral and postdoctoral applicants may be asked to send transcripts prior to award. Unless specified in a particular announcement (RFA/PA), do not include transcripts with the application.</p> <p>Indicate if you previously used another name that is reflected in any of the citations. Manuscripts listed as “pending publication” or “in preparation” should be included and identified.</p>
Attach Current & Pending Support	 <p>Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and AHRQ. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, you will be instructed to refer to the Just-in-Time Policy in Part III, Policies, Assurances, Definitions and Other Information.</p>

Profile – Senior/Key Person [n]









For NIH and AHRQ Fellowships: Profile – Senior/Key Person for Fellowships, Person 1 is the (primary) Sponsor. Additional person profiles (as applicable) can be added for co-sponsor; collaborators; and doctoral dissertation advisor. Click on **Other Project Role** and choose “Other” in the drop down menu, then indicate in the blank “Sponsor” or “Co-Sponsor” as applicable to define the role the person will have in the project.

The remaining Senior/Key Person Profiles should be listed in alphabetical order. While alphabetical order is preferred, it is not required. However, be aware that these profiles will appear in the application in the order provided by the applicant. Therefore, peer reviewers will see them in the order presented.

After providing data for each individual Senior/Key Person, click the **Next Person** button at the bottom of the form to enter data for the next Senior/Key Person. Continue in this manner until data has been provided for up to 40 Senior/Key Persons. To ensure proper performance of this form, after adding 20 additional Senior/Key Persons please save your application, close the Adobe reader, and reopen it. For applications involving more than 40 Senior/Key Persons, the “Additional Senior/Key Person Profiles” fields will become available once data for the first 40 Senior/Key Persons has been provided.

Field Name	Instructions
Prefix	Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the Senior/Key Person.
First Name	Enter the first (given) name of the Senior/Key Person. This field is required.
Middle Name	Enter the middle name of the Senior/Key Person, if applicable.

Field Name	Instructions
Last Name	Enter the last (family) name of the Senior/Key Person. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the name of the Senior/Key Person.
Position/Title	Enter the title of the Senior/Key Person.
Department	Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the Senior/Key Person.
Organization Name	Enter the name of organization of the Senior/Key Person.  This is a required field for applications submitted to NIH and AHRQ.
Division	Enter the name of primary organizational division, office, or major subdivision of the Senior/Key Person.
Street1	Enter first line of the street address for the Senior/Key Person. This field is required.
Street2	Enter second line of the street address for the Senior/Key Person, if applicable. This field is optional.
City	Enter the city for the address of the Senior/Key Person. This field is required.
County/Parish	Enter the county or parish for the address of the Senior/Key Person.
State	Enter the State where the Senior/Key Person is located. This field is required if the Senior/Key Person is located in the United States.
Province	Enter the Province where the Senior/Key Person is located.
Country	Select the country for the Senior/Key Person address. This field is required.
ZIP Code	Enter the nine-digit Postal Code (e.g., ZIP Code) of the Senior/Key Person address. This field is required if the Senior/Key Person is located in the United States.
Phone Number	Enter the daytime telephone number for the Senior/Key Person. This field is required.
Fax Number	Enter the fax number for the Senior/Key Person.

Field Name	Instructions
Email	Enter the email address for the Senior/Key Person. This field is required for the Senior/Key Person.
Credential, e.g., agency login	<p>If you are submitting to an agency (e.g., NIH) where you have an established personal profile, enter the agency ID. If not, leave blank.</p>  <p>For NIH and AHRQ, registration in the eRA Commons is required for all Fellowship applicants (PD/PIs), but is optional for the sponsor and co-sponsor(s). The assigned Commons Username (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and AHRQ. Applications will not pass agency validation requirements without this field.</p>
Project Role	<p>Select one. Use "Other" if a category is not listed in the pick list.</p>  <p>Sponsors, Co-sponsors and doctoral dissertation advisors should use the "Other" category and indicate the appropriate role (e.g. Sponsor) as the role in the "Other Project Role Category."</p>
Other Project Role Category	<p>Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist.</p>  <p>For Fellowships, enter Sponsor, Co-sponsor, Dissertation Advisor(s), Statisticians, and other consultants, as applicable.</p>
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., RN). This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information.
Attach Biographical Sketch	<p>Provide a biographical sketch for the Senior/Key Person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here. This field is required.</p>  <p>Use for Sponsor, Co-sponsor and other Senior/Key Personnel following the format described below.</p>
Attach Current & Pending Support	 <p>Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and AHRQ submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, you will be instructed to refer to the Just-in-Time Policy in Part III, Policies, Assurances, Definitions and Other Information.</p>

Additional Senior/Key Person Profile(s)

If more than forty Senior/Key Person profiles are proposed, enter the information in a separate file and attach it here.



A sample Additional Senior/Key Person Profiles format page for greater than 40 profiles is found under “Additional Format Pages” at: <http://grants.nih.gov/grants/funding/424/index.htm>.

Additional Biographical Sketch(es) (Senior/Key Person)

Provide a biographical sketch for each Senior/Key Person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here.



Biographical Sketches should follow the format described below.

Additional Current and Pending Support(s)

Provide a list of all current and pending support for the PD/PI and each Senior/Key Person (even if they receive no salary support from the project(s) for ongoing projects and pending proposals. Show the total award amount for the entire award period (including indirect costs) as well as the number of person-months per year to be devoted to the project by the Senior/Key Person, regardless of source of support. Concurrent submission of a proposal to other organizations will not prejudice its review.



Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and AHRQ submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, you will be instructed to refer to the [Just-in-Time Policy](#) in Part III, Policies, Assurances, Definitions and Other Information.

Sponsor (Required) and Co-Sponsor (if applicable) Instructions for a Biographical Sketch

The Sponsor and Co-Sponsor(s) click on **Senior/Key Person**. Use the sample *format* on the [Biographical Sketch Format Page](#) to prepare this section for all Fellowship applications. Include biographical sketches of all **Senior/Key Personnel**. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page. See the sample of a [completed Biographical Sketch](#).

If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI but is currently optional for all other Senior/Key Persons. In other federal forms this information is referred to as “Credential, e.g., agency login.” For information on the eRA Commons, see <https://commons.era.nih.gov/commons/index.jsp>.

Complete the educational block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable. For each entry provide the name and location of the institution; the degree received (if applicable); the month and year the degree was received, and the field of study. For residency entries, the field of study section should reflect the area of residency.

Following the educational block, complete sections A, B, C, and D as described below.

- A. Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application.

- B. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- C. **Peer-reviewed publications or manuscripts in press (in chronological order).** NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. 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. 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 acceptable as appendix material).
- D. **Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the Senior/Key Person identified on the Biographical Sketch. *Do not include number of person months or direct costs.*

Don't confuse “Research Support” with “Other Support.” Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. 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. NIH staff will request complete and up-to-date “other support” information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

5. Completing PHS Fellowship Specific Components

5.1 Overview

In conjunction with the SF424 (R&R) components, NIH and AHRQ Fellowship applicants should also complete and submit additional components in the “PHS Fellowship Supplemental Form.” Note the PHS Fellowship components include additional data required by the agency for a complete application. While these are not identical to the PHS Fellowship application form pages, the PHS Fellowship reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R)

components. A complete application to NIH and AHRQ will include SF424 (R&R) and PHS Fellowship components.

The PHS Fellowship components include:

- Cover Letter Component (Required)
- PHS Fellowship Supplemental Form (Parts A-E)

Complete each component using the instructions provided below.

5.2 Cover Letter Component

PHS Cover Letter

OMB Numbers: 0925-0001
0925-0002

*Mandatory Cover Letter Filename:

Fellowship applicants are required to include a cover letter with the application. The cover letter is only for internal use and will not be shared with peer reviewers. The cover letter must contain the same list of referees (including name, department affiliation, and institution) that is included in the Other Project Information Component Item 12, Other Attachments. It should also contain any of the following information that applies to the application:

1. Application title.
2. Funding Opportunity (PA or RFA) title of the NIH initiative.
3. Request of an assignment (referral) to a particular [awarding component](#) (e.g. NIH IC) or [Scientific Review Group \(SRG\)](#). The PHS makes the final determination.
4. List of individuals (e.g., competitors) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.
6. For late applications (see Late Application policy in [Section 2.14](#)) include specific information about the timing and nature of the cause of the delay.
7. When submitting a Changed/Corrected Application **after** the submission date, a cover letter is **required** explaining the reason for the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters until after an application is

verified; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.

8. Statement that you have attached any required agency approval documentation for the type of application submitted.
9. The same list of referees (including name, department affiliation, and institution) that is included in the Other Project Information Component Item 12, Other Attachments.

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)].

Save this information in a single file in a location you remember and convert the file to PDF. Click **Add Cover Letter File**, browse to where you saved the file, select the file, and then click **Open**. The name of the file attached will automatically appear in the “Mandatory Cover Letter Filename” field.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name

to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

5.3 PHS Fellowship Supplemental Form

PHS Fellowship Supplemental Form
OMB Number: 0925-0002

A. Application Type:

From SF424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated here for your reference as you provide the responses that are appropriate for this Fellowship application.

New
 Resubmission
 Renewal
 Continuation
 Revision

B. Research Training Plan

1. Introduction to Application <small>(for RESUBMISSION applications only)</small>	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
2. * Specific Aims	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
3. * Research Strategy	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
4. Inclusion Enrollment Report <small>(for RENEWAL applications only)</small>	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
5. Progress Report Publication List <small>(for RENEWAL applications only)</small>	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

Human Subjects

Please note. The following item is taken from the Research & Related Other Project Information form. The response provided on that page, regarding the involvement of human subjects, is repeated here for your reference as you provide related responses for this Fellowship application. If you wish to change the answer to the item shown below, please do so on the Research & Related Other Project Information form; you will not be able to edit the response here.

Are Human Subjects Involved? Yes No

6. * Human Subjects Involvement Indefinite? Yes No

7. Clinical Trial? Yes No

8. Agency-Defined Phase III Clinical Trial? Yes No

9. Protection of Human Subjects	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
10. Inclusion of Women and Minorities	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
11. Targeted/Planned Enrollment	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
12. Inclusion of Children	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

Other Research Training Plan Sections

Please note. The following item is taken from the Research & Related Other Project Information form. The response provided on that page, regarding the use of vertebrate animals, is repeated here for your reference as you provide related responses for this Fellowship application. If you wish to change the answer to the item shown below, please do so on the Research & Related Other Project Information form; you will not be able to edit the response here.

Are Vertebrate Animals Used? Yes No

13. * Vertebrate Animals Use Indefinite? Yes No

14. Vertebrate Animals	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
15. Select Agent Research	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
16. Resource Sharing Plan	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
17. * Respective Contributions	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
18. * Selection of Sponsor and Institution	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
19. * Responsible Conduct of Research	<input type="text"/> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

PHS Fellowship Supplemental Form

C. Additional Information

Human Embryonic Stem Cells

1. * Does the proposed project involve human embryonic stem cells? Yes No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s), using the registry information provided within the agency instructions. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the Registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s):

Fellowship Applicant

2. Alternate Phone Number:

3. Degree Sought During Proposed Award:

Degree:

If "other", please indicate degree type:

Expected Completion Date (month/year):

4. * Field of Training for Current Proposal:

5. * Current Or Prior Kirschstein-NRSA Support? Yes No

If yes, please identify current and prior Kirschstein-NRSA support below:

* Level	* Type	Start Date (if known)	End Date (if known)	Grant Number (if known)	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Reset Entry"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Reset Entry"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Reset Entry"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Reset Entry"/>

6. * Applications for Concurrent Support? Yes No

If yes, please describe in an attached file:

7. * Goals for Fellowship Training and Career

8. * Activities Planned Under This Award

9. Doctoral Dissertation and Other Research Experience

10. * Citizenship: U.S. Citizen or noncitizen national Permanent Resident of U.S. Pending
 Permanent Resident of U.S. Non-U.S. Citizen with temporary U.S. visa
(If a permanent resident of the U.S., a notarized statement must be provided by the time of award)

PHS Fellowship Supplemental Form

C. Additional Information (continued)

Institution

11. Change of Sponsoring Institution Name of Former Institution:

D. Budget

All Fellowship Applicants:

1. * Tuition and Fees:

None Requested Funds Requested:

Year 1	<input style="width: 90%;" type="text"/>
Year 2	<input style="width: 90%;" type="text"/>
Year 3	<input style="width: 90%;" type="text"/>
Year 4	<input style="width: 90%;" type="text"/>
Year 5	<input style="width: 90%;" type="text"/>
Year 6 (when applicable)	<input style="width: 90%;" type="text"/>
Total Funds Requested:	<input style="width: 90%;" type="text"/>

Senior Fellowship Applicants Only:

	Amount	Academic Period	Number of Months	
2. Present Institutional Base Salary:	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>	<input type="button" value="Reset Entry"/>

3. Stipends/Salary During First Year of Proposed Fellowship:

	Amount	Number of Months	
a. Federal Stipend Requested:	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>	
	Amount	Number of Months	
b. Supplementation from other sources:	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>	
	Type (sabbatical leave, salary, etc.)		
	<input style="width: 90%;" type="text"/>		
	Source		
	<input style="width: 90%;" type="text"/>		

E. Appendix

It is strongly recommended that fellowship applicants and sponsors speak with a PHS Program Official for Institute or Center (IC) specific guidance before preparing this application. A list of contacts specifically for extramural training at the NIH ICs can also be found at: <http://grants.nih.gov/training/>

[tac_training_contacts.doc](#). For AHRQ, see <http://www.ahrq.gov/fund/training/trgstaff.htm>. Individuals always are encouraged to check these Web sites for the most current contact information.

Note: Required fields on the PHS Fellowship Supplemental Form are noted with an asterisk(*).

Field Name	Instructions
A. Application Type	This field is pre-populated from the SF424 (R&R) Cover Component. Corrections to this field must be made in that component.
B. Research Training Plan	<p>The Research Training Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies. This section should be well-formulated and presented in sufficient detail that it can be evaluated for both its research training potential and scientific merit. It is important that it be developed in collaboration with your sponsor, but it should be written by you, the fellowship applicant.</p> <p>Research Training Plan Attachments</p> <p>(Also, see Section 2.3.2 - Creating PDFs for Text Attachments and Section 2.6 - Format Specifications for Text (PDF) Attachments of the SF424(R&R) Application Guide)</p> <p>Although many of the sections of this application are separate PDF attachments, page limitations referenced in the instructions and/or funding opportunity announcement must still be followed. Agency validations will include checks for page limits (and use of appropriate font). Some accommodation will be made for sections that, when combined, must fit within a specified limitation.</p> <p>NIH and other PHS agencies require all text attachments to the SF424(R&R) application forms to be submitted as PDF files.</p> <p>Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. Scanning paper documents, without the proper Optical Character Recognition (OCR) process, will hamper automated processing of your application for NIH analysis and reporting.</p> <p>Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.</p> <p>Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, fellowship 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.</p> <p>Full-sized glossy photographs of material such as electron micrographs or gels must only be included within the page limitations of the Research Strategy section. The maximum size of images to be included should be approximately 1200 x 1500</p>

Field Name	Instructions
	<p>pixels using 256 colors. Figures must be readable as printed on an 8.5 x 11 inch page at normal (100%) scale.</p> <p>Investigators must use image compression such as JPEG or PMG. Do not include figures or photographs as separate attachments either in the Appendix or elsewhere in the application.</p> <p>Separate Attachments</p> <p>Separate attachments have been designed for the Research Training Plan sections to maximize automatic validations conducted by the eRA system. When the application is received by the agency, all of the Research Training Plan sections will be placed in the appropriate order so that reviewers and agency staff will see a single cohesive Research Training Plan.</p> <p>When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document after it has been attached, you must delete the previous attachment and then reattach the revised document to the application form. Use the “View Attachment” button to determine if the correct version has been attached.</p> <p>Page Limitations</p> <p>All applications for funding must be self-contained within specified page limitations. Agency validations will include checks for page limits. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they do not replace the validations conducted by Agency staff. Applications found not to comply with the requirements may be delayed in the review process.</p> <p>The following page limits apply to fellowship applicants only, unless specified otherwise in the FOA. All page limits include all tables, graphs, figures, diagrams and charts.</p> <ul style="list-style-type: none"> • Introduction – resubmissions and revisions only; limited to one page. • Specific Aims – limited to one page. • Research Strategy – limited to six pages. <p>Be succinct and remember that there is no requirement to use all six pages allotted to the Research Strategy.</p> <p>Note that the Research Training Plan PDF may include graphic images of gels, micrographs, photographs, etc.; however these images may not be included in the Appendix (except when part of a qualifying publication).</p> <p>Unless otherwise specified in a PHS solicitation, Internet Web site addresses (URLs) may not be used to provide information necessary to the review, except for reference citations, because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an internet site as it could compromise their anonymity.</p> <p>Note: Begin each text section of the Research Training Plan with a section header</p>

Field Name	Instructions
	<p>(e.g., Introduction, Specific Aims, Research Strategy, etc.).</p> <p>Research Training Plan of Resubmission Applications</p> <p>A resubmission application must include substantial changes. If the summary statement cites weaknesses specifically to the Research Training Plan, identify these changes in the resubmitted Research Training Plan clearly by bracketing, indenting, or changing typography, unless the changes are so extensive as to include most of the text. This exception should be explained in the Introduction. Do not underline or shade changes. Application processing may be delayed or the application may be returned if it does not comply with all of these requirements.</p> <p>Include sufficient information to permit an effective review without reviewers having to refer to any previous application.</p>
<p>1. Introduction to Application (Resubmission Applications Only)</p>	<p>Attach for all resubmission applications an Introduction of no more than one page that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to criticisms and issues raised in the summary statement for the previous application. See specific instructions in Part I Section 2.7, Resubmission Applications, on the content of the Introduction.</p> <p>The Introduction is limited to one page unless specified in the FOA.</p> <p>First time (new) applications should not include an Introduction unless specified in the FOA.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>2. Specific Aims</p>	<p>State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.</p> <p>List succinctly the specific objectives of the 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.</p> <p>Specific Aims are limited to one page.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>3. Research Strategy</p>	<p>Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (Part I Section 4.4.9). Research Strategy is limited to six pages.</p> <p>Follow the page limits for the Research Strategy in the table of page limits (Table</p>

Field Name	Instructions
	<p>2.6-1), unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.</p> <p><u>(a) Significance</u></p> <ul style="list-style-type: none"> • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. <p><u>(b) Innovation</u> - Fellowship applications should not include an Innovation section unless specified in the FOA.</p> <p><u>(c) Approach</u></p> <ul style="list-style-type: none"> • Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 16 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. • If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. • Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in Item 15, below. • Include any courses that you plan to take to support the research training experience. <p>As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.</p> <p>Preliminary Studies for New Applications.</p> <p>For new applications, include information on preliminary studies, if any, as part of the Approach section. Discuss the applicant's preliminary studies, data and/or experience pertinent to this application.</p> <p>When applicable, provide a succinct account of published and unpublished results, indicating progress toward their achievement.</p> <p>Progress Report for Renewal Applications.</p> <p>Renewal applications for individual fellowships are rare. You should consult with your program official before preparing such an application.</p> <p>In the rare instance that you are submitting a renewal application, provide a Progress</p>

Field Name	Instructions
	<p>Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions.</p> <p>A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in Section 5; do not include that information here.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>4. Inclusion Enrollment Report (for RENEWAL applications only)</p>	<p>In the rare instance that you are submitting a renewal application, and it involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender. See Part II, Section 4.3 for more detailed instructions on which Target and Enrollment Report or Table to use. (Not part of the page limitations of the Research Training Plan.)</p> <p>If submitting a resubmission of a renewal, this upload will not be available. Instead, the Inclusion Enrollment Report required in the PHS Fellowship Supplemental Form component (Item 4) should be saved as an individual pdf file titled “Inclusion_Enrollment_Report.pdf” and attached in Item 12 (Other Attachments) of the SF424 (R&R) Other Project Information component.</p>
<p>5. Progress Report Publication List (for RENEWAL applications only)</p>	<p>In the rare instance that you are submitting a renewal application, list the titles 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. For NIH applications only, when citing articles that fall under the NIH Public Access Policy, http://publicaccess.nih.gov/, were authored or co-authored by the fellowship 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.</p> <p>Citations that are not covered by the NIH 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 E. Appendix below).</p> <p>If submitting a resubmission of a renewal, this upload will not be available. Instead, the Progress Report Publication List (Item 5) should be saved as an individual pdf file titled “Progress_Report_Publication_List.pdf” and attached in Item 12 (Other Attachments) of the SF424 (R&R) Other Project Information component.</p>

Field Name	Instructions
Human Subjects	<p>Prefilled from the Research and Related Other Project Information form. If activities involving human subjects are not planned at any time during the proposed project at any performance site, skip the remainder of the block and continue to Other Research Training Plan Sections. If you have indicated “Yes” for Human Subjects involvement, consult with your Sponsor and Administrative Officials at the Sponsoring Institution before completing this section, and refer to Part II Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan. Human subjects requirements may apply even if you are obtaining specimens/data from collaborators or if you are subcontracting the human research to another organization. For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children. The Scientific Review Group (SRG) will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. The evaluation of the inclusion plans will be factored into the overall score that the SRGs award for scientific and technical merit of the application. Much of the information on the protection of human subjects that you are required to provide in the Fellowship application is identical to information that you will be required to provide for IRB review at your own institution.</p> <p>Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.</p>
6. Human Subjects Involvement Indefinite?	<p>Check “Yes” if at the time of application plans to involve human subjects are unknown. If an award is made, the fellow may not participate in human subjects research until an updated research training plan is submitted and approved by the awarding component. Such a plan must be developed in consultation with the sponsor. Certification of the date of IRB approval must also be submitted before the fellow can participate in human subjects research.</p>
7. Clinical Trial	<p>Check the “Yes” or “No” box to indicate whether the project is a 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).</p>

Field Name	Instructions
8. Agency-Defined Phase III Clinical Trial?	<p>Check the “Yes” or “No” box to indicate whether the project is an 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 either evaluating an experimental intervention in comparison with a standard or control intervention or of 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.</p>
9. Protection of Human Subjects	<p>Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan.</p> <p>This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&R Other Project Information form. If the answer is “No” to the question but the proposed research involves human specimens and/or data from subjects applicants must provide a justification in this section for the claim that no human subjects are involved.</p> <p>Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
10. Inclusion of Women and Minorities	<p>Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&R Other Project Information form and the research does not fall under Exemption 4.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
11. Targeted/Planned Enrollment (Clinical Research Only)	<p>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 Human Subjects Section of the Research Plan, Section 4.3. For applicants answering “Yes” to the question “Are human subjects involved?” on the R&R Other Project Information Form and the research does not fall under Exemption 4, complete the Targeted/Planned Enrollment Table for each protocol.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>

Field Name	Instructions
<p>12. Inclusion of Children</p>	<p>Refer to Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Sections 4.4 and 5.7. For applicants answering “Yes” to the question “Are human subjects involved” on the R&R Other Project Information Form and the research does not fall under Section 4, this section is required .</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>Other Research Training Plan Sections</p>	<p>Consult with your Sponsor and Administrative Officials at the Sponsoring Institution before completing Items 13 through 17 and 19.</p>
<p>Are Vertebrate Animals Used?</p>	<p>Prefilled from the Research and Other Project Information form. If activities involving vertebrate animals are not planned at any time during the proposed project at any performance site, indicate no and skip items #13 and #14.</p>
<p>13. Vertebrate Animals Use Indefinite?</p>	<p>If the sponsoring institution has an approved Animal Welfare Assurance on file with the NIH Office of Laboratory Animal Welfare (OLAW) but, at the time of application, plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, check "Yes." If an award is made, vertebrate animals may not be involved until a verification of the date of IACUC approval has been submitted to the NIH IC or AHRQ.</p>
<p>14. Vertebrate Animals</p>	<p>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 site(s)), 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 impact/priority score may be negatively affected. The five points are as follows:</p> <ol style="list-style-type: none"> 1. Provide a detailed description of the proposed use of the animals in the work outlined in the “Research Strategy” 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.

Field Name	Instructions
	<p>5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, present a justification for not following the recommendations.</p> <p>If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to the involvement of animals the grantee must submit to the NIH awarding office detailed information as required in points 1-5 above and verification of IACUC approval. If the grantee does not have an Animal Welfare Assurance then an appropriate Assurance will be required (See Part III, Section 2.2 Vertebrate Animals for more information).</p> <p>Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>15. Select Agent Research</p>	<p>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.</p> <p>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 73.3, 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.</p> <p>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 your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.</p> <p>If any of the activities proposed in your application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other 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.</p> <ol style="list-style-type: none"> 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. <ul style="list-style-type: none"> • If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed. <p>*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.”</p>

Field Name	Instructions
	<p>3. Provide a description of all facilities where the Select Agent(s) will be used.</p> <ul style="list-style-type: none"> • 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). • Describe the biocontainment resources available at all performance sites. <p>If you are responding to a specific funding opportunity announcement, address any requirements specified by the FOA.</p> <p>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.</p> <p>Save this file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>16. Resource Sharing Plan(s)</p>	<p>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. See Part III, 1.5 Sharing Research Resources.</p> <p>1. <i>Data Sharing Plan</i>: Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&A) 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 Funding Opportunity Announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.</p> <p>2. <i>Sharing Model Organisms</i>: If the development of model organisms is anticipated, attach a description of a specific plan for sharing and distributing unique model organism research resources or state appropriate reasons why such sharing is restricted or not possible. For many individual fellowships it is anticipated that plans of this nature would have already been reported to the NIH by your sponsor in his/her research application. When this has occurred, indicate so in this section and include the appropriate grant number. For additional information on this policy, see Sharing Model Organisms in Part III, 1.3.2.</p> <p>3. <i>Genome-Wide Association Studies (GWAS)</i>: 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 (e.g., blood pressure or weight)</p>

Field Name	Instructions
	<p>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 (NOT-OD-07-088) and http://grants.nih.gov/grants/gwas/.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>17. Respective Contributions</p>	<p>Describe the collaborative process between you and your sponsor/co-sponsor in the development, review, and editing of this research training plan. Discuss the respective roles in accomplishing the proposed research. Limited to one page.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>18. Selection of Sponsor and Institution</p>	<p>Describe the rationale/justification for the selection of the sponsor and institution.</p> <ol style="list-style-type: none"> 1. Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the sponsoring organization, provide an explanation here. 2. Doctorate or Current Institution. (For postdoctoral and senior fellows only) Since training is expected to broaden a fellow's perspective, postdoctoral fellowship applicants requesting training at either their doctorate institution or at the institution where they have been training for more than a year must explain why further training at that institution would be valuable. Individuals applying for Senior Fellowships who are requesting training at the institution at which they are employed should provide a similar explanation. 3. Foreign Institution. If you are proposing a research training experience at a foreign institution, show that the foreign institution and sponsor offer special opportunities for training that are not currently available in the United States. Key factors in the selection of a foreign institution should be described. If applicable, the need for and level of proficiency in reading, speaking, and comprehending the foreign language should be addressed. <p>Selection of Sponsor and Institution is limited to one page.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>19. Responsible Conduct of Research</p>	<p>Note: No award will be made if an application lacks this component.</p> <p>Every fellow must receive instruction in the responsible conduct of research (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html) appropriate to the career stage of the applicant. The section must document prior participation or instruction in responsible conduct of research during the applicant's current career stage (including the date instruction was last completed) and propose a plan to either receive instruction in responsible conduct of research or participate as a course</p>

Field Name	Instructions
	<p>lecturer, etc., depending on the applicant's career stage. Applications must include a description, limited to no more than one page, of the sponsoring institution's plans to provide, and the fellowship applicant's plans for obtaining, instruction in the responsible conduct of research, including the format, subject matter, faculty participation, duration and frequency of instruction. The plan should be tailored to the needs of the fellow, and may go beyond formal institutional courses and provide opportunities for the individual to develop their own scholarly understanding of the ethical issues associated with their research activities and their impact on society. The role of the sponsor in the instruction in responsible conduct of research must be described.</p> <p>See Part III, 1.16 for additional information.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
C. Additional Information	
1. Human Embryonic Stem Cells	<p>Indicate "Yes" if the proposed research involves human embryonic stem cells. See http://stemcells.nih.gov/index.asp for a definition of human embryonic stem cells. If the proposed project involves human embryonic stem cells, list in this section the 4-digit NIH Registration Number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry found at: http://grants.nih.gov/stem_cells/registry/current.htm. If a specific stem cell line cannot be referenced at the time of application submission, check the box provided to indicate that one from the registry will be used.</p>
Fellowship Applicant	
2. Alternate Phone Number	<p>Enter an alternate phone number (e.g., cell phone) where the fellowship applicant can be reached on matters relating to this application for fellowship support. This should be a different number than provided in the PD/PI contact information in the Cover Component.</p>
3. Degree Sought During Proposed Award	<p>Complete if applicable. Completion of the degree requirements should be coordinated with the sponsor. The fellowship applicant must select the degree from the drop down menu and also enter the month and year of the expected completion date. If the degree is not on the drop down menu, please mark "Other" and indicate the type of degree in the space provided.</p>

Field Name	Instructions
<p>4. Field of Training for Current Proposal</p>	<p>Indicate the proposed area of research training according to the Fields of Training (FOT) codes listed in the drop down menu. Provide the FOT code that best describes the proposed area of research training from the FOT codes listed in the instructions. Select the subcategory descriptor, unless the broader category (in bold uppercase) fits best. If the FOT listing does not provide a good descriptor, select “Other.” (This information is used for reporting purposes only and is not used for study section assignments.)</p>
<p>5. Current or Prior Kirschstein-NRSA Support?</p>	<p>If “Yes”, identify the current and/or prior Kirschstein-NRSA support from the drop down menu, up to four entries. Define level of support as either predoctoral or postdoctoral level (not the level of experience). The type of support is either individual fellowship or institutional research training grant indicated on the drop down menu. Enter the start and end dates (if known) of the support (month, day, and year) and the grant number (if known) of the current and/or prior support (e.g., T32 GM123456 or F31 HL345678).</p> <p>An individual cannot receive more than 5 years of cumulative predoctoral Kirschstein-NRSA support and 3 years cumulative postdoctoral Kirschstein-NRSA support (the total of Institutional Grants and Individual Fellowships) without a waiver from the NIH IC. The NIH ICs have different policies on waiving the statutory limits on support. Therefore, the fellowship applicant must request a waiver from the probable funding IC before requesting a period of support that would exceed these limits. The fellow’s sponsor and a sponsoring institution official must endorse the request, and it must include justification and specify the amount of additional support for which approval is sought. Individuals seeking additional support beyond the third year of postdoctoral support are strongly advised to consult with their awarding IC Program Officer before submitting a waiver request. It is important to read carefully the applicable FOA that may have an overall approval to exceed these limits (e.g., the F30 combined M.D./Ph.D. program allows for up to 6 years of predoctoral support).</p> <p>Promptly report to the NIH IC to which this application is assigned any additional NRSA support received while this application is pending.</p>
<p>6. Applications for Concurrent Support?</p>	<p>Check the appropriate answer, indicating “Yes” if the fellowship applicant has applied or will be applying for other support that would run concurrently with the period covered by this application. Include the type, dates, source(s) and amount in the attachment document. The fellowship applicant must promptly report to the NIH IC to which this application is assigned, or AHRQ, any support resulting from other such applications.</p> <p>Limited to one page.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>

Field Name	Instructions
<p>7. Goals for Fellowship Training and Career</p>	<p>The fellowship applicant must describe his/her overall career goals, and explain how the proposed research training will enable the attainment of these goals. Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award.</p> <p>Limited to one page.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>8. Activities Planned Under This Award</p>	<p>The fellowship applicant must describe by year the activities (research, coursework, etc.) he/she will be involved in under the proposed award and estimate the percentage of time to be devoted to each activity, based on a normal working day for a full-time fellow as defined by the sponsoring institution. The percentage should total 100 for each year. Also, briefly explain activities other than research and relate them to the proposed research training.</p> <p>For postdoctoral fellowships (F32), do not exceed three years. For senior fellowships (F33) do not exceed two years. Predoctoral fellowships (F31), including fellowship applicants for the M.D./Ph.D. (F30) program may reflect up to six years if allowed by the applicable FOA.</p> <p>Limited to one page.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>9. Doctoral Dissertation and Research Experience</p>	<p>Summarize your research experience (limited to 2 pages) in chronological order.</p> <p>Advanced graduate students, who have (or will have) completed their comprehensive examinations by the time of award must also include a narrative of their doctoral dissertation (may be preliminary). If you have no research experience, list other scientific experience. Do not list academic courses.</p> <p>In summarizing their research experience, Postdoctoral and Senior Fellowship applicants should include the areas studied and conclusions drawn.</p> <p>Postdoctoral fellowship applicants should also specify which areas of research were part of their thesis or dissertation and which, if any, were part of a previous postdoctoral project.</p> <p>Limited to two pages.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>10. Citizenship</p>	<p>Fellowship applicants must check the appropriate box. To be eligible for a Kirschstein-NRSA Individual Fellowship (F30, F31, F32, F33), the fellowship applicant must be a U.S. citizen, a non-citizen national, or have been lawfully</p>

Field Name	Instructions
	<p>admitted to the U.S. for permanent residence before the award is issued. U.S. non-citizen nationals are persons born in lands that are not States but are under U.S. sovereignty, jurisdiction, or administration, e.g., American Samoa. Individuals on temporary student visas are not eligible for NRSA support.</p> <p>If the fellowship applicant has been lawfully admitted for permanent residence, i.e., is in possession of a Permanent Resident Card (USCIS Form I-551) or other legal verification of such status, the fellowship applicant should check the “Permanent Resident of U.S.” box. Before the award is issued, a permanent resident will be required to submit a notarized statement that a licensed notary has seen the fellowship applicant’s valid Permanent Resident Card (USCIS Form I-551) or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S.</p> <p>If the fellowship applicant is a non-citizen of the U.S. who has applied for, but not yet been granted legal admission to the U.S. as a permanent resident, the applicant should check the “Permanent Resident of U.S. Pending” box, understanding that no award will be issued until such time as the required permanent residency has been established and the required documentation submitted to NIH or AHRQ.</p> <p>If the fellowship applicant is applying for a non-NRSA fellowship program supported by the NIH, for which citizenship or permanent residency is not required (e.g., Fogarty International Center programs), the fellowship applicant must have in his/her possession a valid visa allowing him/her to remain in the U.S. (or in a foreign research training setting, if applicable) long enough to be productive on the proposed fellowship project. It is the responsibility of the sponsoring institution to determine and retain documentation indicating that the individual fellowship applicant’s visa will allow him/her to reside in the proposed research training setting for the period of time necessary to complete the proposed fellowship. The fellowship applicant should check the “Non-U.S. Citizen with temporary U.S. visa” box. Verification may be requested by the NIH IC prior to issuance of an award. In general, it is highly recommended that all non-U.S. citizens adhere to specific requirements as stated in the FOA or contact the appropriate individual listed on the FOA.</p>
Institution	
11. Change of Sponsoring Institution	The fellowship applicant must indicate if this application is being submitted with a change of sponsoring institution. If the fellowship applicant checks the box, the name of the former sponsoring institution must be provided.
D. Budget	

Field Name	Instructions
<p>All Fellowship Applicants:</p> <p>1. Tuition and Fees:</p>	<p>All fellowship applicants should list the estimated costs of tuition and fees. Postdoctoral and senior fellowship applicants should list the costs associated with courses planned that support the research training experience and are identified and described in the attachment for the Research Strategy section of the Research Training Plan in Section B. If no tuition and fees are being requested, check the box provided.</p> <p>In accordance with NIH Guide NOT-OD-06-093, funds to offset the costs of health insurance (self or family, as appropriate) are included in the standard Institutional Allowance, and not to be requested as part of Tuition and Fees.</p>
<p>Senior Fellowship Applicants Only:</p> <p>2. Present Institutional Base Salary:</p>	<p>Senior fellowship applicants must provide their present base salary and indicate the period of time on which the salary is determined (e.g., academic year of 9 months, full-time 12 months, etc. The number may not be more than 12, but may include a decimal indicating partial months (e.g., 9.5).</p>
<p>Senior Fellowship Applicants Only:</p> <p>3. Stipend/ Salary During First Year of Proposed Fellowship:</p>	<p>a. Federal Stipend Requested: Fellowship applicants must insert the stipend being requested for the initial period of support and the number of months.</p> <p>b. Supplementation from other sources: Fellowship applicants should enter the anticipated amount and the length of time associated with the amount. Enter also the type of supplementation expected (e.g., salary, sabbatical leave, etc.) and the source of such funding.</p>
<p>E. Appendix</p>	<p>Only one copy of appendix material should be included.</p> <p>A maximum of 10 PDF attachments is allowed in the Appendix. Grants.gov defaults to a maximum of 10 separate attachments. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. Publications that are publicly accessible must not be included in the appendix. When allowed there is a limit of three publications that are not publicly available (see below for further details and check the FOA for any specific instructions), though not all fellowship activity codes allow publications to be included in the appendix.</p> <p>Do not use the Appendix to circumvent the page limitations of the Research Strategy section of the Research Training Plan.</p> <p>Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the</p>

Field Name	Instructions
	<p>appendix requirements may be delayed in the review process.</p> <p>New, resubmission, renewal, and revision applications may include the following materials in the Appendix:</p> <ul style="list-style-type: none"> • Publications – No longer allowed as appendix materials except in the circumstances noted below. Fellowship applicants may submit up to 3 of the following types of publications: <ul style="list-style-type: none"> ○ Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment. ○ Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment. ○ Patents directly relevant to the project: The entire document should be submitted as a PDF attachment. <p>Do not include unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication.</p> <ul style="list-style-type: none"> • Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the Appendix as necessary. • For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), fellowship applicants should contact the SRO for instructions following notification of assignment of the application to a study section. Fellowship applicants are encouraged to be as concise as possible and submit only information essential for the review of the application. <p>Items that must not be included in the appendix:</p> <ul style="list-style-type: none"> • Photographs or color images of gels, micrographs, etc. are no longer accepted as Appendix material. These images must be included in the Research Training Plan PDF. However, images embedded in publications are allowed. <p>Publications that are publicly accessible. 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 section, the Progress Report Publication List section, and/or the Biographical Sketch section.</p>

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

5.4 Letters of Reference (must be submitted electronically on the specified Fellowship Reference Form through the eRA Commons)

IMPORTANT NOTE: This section contains instructions for both the Fellowship Applicant (Part A) and the Referees (Part B). Applicants are urged to read both sections carefully so they are able to provide accurate instructions to the Referees. Failure to submit all of the required reference in the appropriate format may result in the application being returned to you without review.

Part A. Instructions for Fellowship Applicants:

Letters of reference are an important component of the application for the Individual Fellowship Awards. Applicants must arrange to have at least three (and no more than five) references submitted using the [Fellowship Reference Form](https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp) on their behalf to the eRA Commons Web site at <https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp>.

Your referees should be carefully selected. Only those individuals who can make the most meaningful comments about your qualifications for a research career should be used. *The sponsor of this application cannot be counted as a reference. The sponsor's recommendation is included as part of the application (See Sponsor/Co-Sponsor Information).* Whenever possible, select at least one referee (respondent) who is not in your current department. If not submitting a reference from the dissertation advisor or chief of service, provide an explanation in Item 12 – Other Attachments on the SF424 (R&R) Other Project Information Form. For postdoctoral applications, references from graduate or medical school are preferred over those from undergraduate school. Note: For resubmission applications, it is critical that NEW Letters of Reference be submitted (using the appropriate form) providing an up-to-date evaluation of the Fellowship applicant's potential to develop as an independent and productive researcher, and the continued need for additional supervised research experience.

Electronic submission of a letter of reference is a separate process from submitting an application electronically. Reference forms are submitted directly through the eRA Commons and do not use Grants.gov. Therefore, this process requires that the referee provide information including (a) the PD/PI (Fellowship applicant) Commons user name, (b) the PD/PI first and last name as they appear on the PD/PI's Commons account, and (c) the number assigned to the Funding Opportunity Announcement (FOA) under which the Fellowship applicant is applying. The FOA number provided to referees **must** be the FOA number under which the application is submitted; otherwise, the reference letters will not be matched up with the application in the eRA Commons.

Request reference letters only from individuals who will be able to submit them in time for the application receipt date. Consider any factor (e.g., illness or extended vacation) that might cause an inordinate delay. Give these reference instructions to the referees well in advance of the application submission date.

For electronically submitted applications that involve separately submitted confidential reference forms, a feature has been added to monitor electronically the submission of these forms. This monitoring feature appears within the eRA Commons Personal Profile where a Reference Letter menu choice now appears. This feature lists only data items appropriate for monitoring the submission of reference forms but does not provide access to the actual documents. Failure to provide references may delay processing of your application or may result in the application being returned to you without review.

Be sure to list the names of those individuals writing a reference letter on your behalf as an attachment titled "List of Referees" in Item 11, "Other Attachments." This same list must be included in the cover letter.

Confirmation emails will be sent to both the referee and the applicant following electronic form submission. The confirmation sent to the applicant will include the referee's name and the date the form was submitted. The confirmation sent to the referee will include the referee and applicant's names, a confirmation number, and the date the form was submitted.

The applicant and the AOR/SO may check the status of submitted forms by logging into their Commons account and accessing the "check status" screen for this application. The applicant is responsible for reviewing the status of submitted forms and contacting referees to ensure that forms are submitted by the receipt deadline. While the applicant is able to check on the status of the submitted forms, the forms are confidential and he/she will not have access to the forms themselves. Note reference letters can be submitted at any time prior to the receipt deadline. It is **not** necessary to wait until after the application is submitted before reference letters are submitted; the two submissions are distinct.

Applicants should provide the following instructions to their referees (a quick link to this section is http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_Fellowship_VerB.pdf #RefereeInstruct).

Part B. Instructions for Referees:

In two pages or less, describe the applicant's potential for a research career using the [Fellowship Reference Form](#), available in Microsoft Word.

The Fellowship Reference Form **must** be used to evaluate the applicant. The form has three sections. One section is used to compare the applicant to other individuals of similar training and experience that you have known. The second section is used to enter your evaluation. The form will automatically expand to an additional page as you enter your evaluation. The third section is the Referee information section.

Please put the name of the applicant at the top of the form. Also, be sure to include your name and title in the form. Forms may be submitted to the eRA Commons at <https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp> and may be submitted any time after the Funding Opportunity Announcement opens and not later than 5 business days after the application receipt due date.

The following information will be entered by the referee on the on-line form in the eRA Commons at the time of submission:

- Referee First Name (Required)
- Referee Last Name (Required)
- Referee MI Name (middle initial) (Not Required)
- Referee Email (Required)
- Referee Institution/Affiliation (Required)
- Referee Department (Required)
- PD/PI (Fellowship applicant) Commons User ID (Required)
- PD/PI's Last Name, as it appears on the PD/PI's Commons account (Required) (will be validated to ensure they match)
- Funding Opportunity Announcement Number (Required and **must** match the number of the FOA under which the application is being submitted)
- Reference Letter Confirmation Number (Required only if resubmitting a reference form; not required otherwise)
- Fellowship Reference Form – two pages maximum. Complete the format page using word processing software and then convert to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. Additional tips for creating PDF files can be found at http://era.nih.gov/ElectronicReceipt/pdf_guidelines.htm.

Note reference letters can be submitted at any time prior to the receipt deadline. It is **not** necessary to wait until after the application is submitted before reference letters are submitted; the two submissions are distinct. After you have submitted your Reference Letter, both you and the applicant will receive a confirmation of receipt by email. Your email confirmation will include a Reference Letter Confirmation Number. The Confirmation Number will be required when resubmitting reference forms. Please print the confirmation email for your records.

5.5 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 of fellowship applications is performed by senior staff of the potential awarding IC. Only the NIH IC may make actual funding decisions.

A detailed description of what happens to your individual fellowship application after it is received for peer review can be found at the following location:

<http://cms.csr.nih.gov/AboutCSR/OverviewofPeerReviewProcess.htm>. Additional information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate agency.

Discussed and Not Discussed Applications

The initial scientific peer review of individual fellowship applications will also include a process in which only those applications deemed by the reviewers to have the highest scientific and technical merit, generally the better half of the applications under review, will be discussed at the SRG meeting, assigned an impact/priority score, and receive a second level review. Applications in the lower half are reviewed by SRG members but they are not discussed or assigned numerical impact/priority scores 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/priority score for that application (see below). The preliminary impact/priority scores will be used to determine which Fellowship applications will be discussed.

Scoring

SRG members are instructed to evaluate individual fellowship applications by addressing the scored review criteria (see below) and additional review criteria as applicable for the application. However, Funding Opportunity Announcements (FOAs) may list different and/or additional review criteria and considerations.

For each application that is discussed, a final overall impact/priority score will be given by each eligible committee member (without conflicts of interest) following the panel discussion. Each member's impact/priority 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/priority score for each discussed application will be determined by calculating the arithmetic average of all the eligible members' impact/priority 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, 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 SRO's summary of the members' discussion during the SRG meeting; the final impact/priority score; the recommendations of the SRG, 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 scored review criteria will be reported individually on the Summary Statement. Numerical impact/priority scores are not given for applications that are not discussed.

Individual Fellowship Application Review Criteria

Overall Impact/Merit. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood that the fellowship will enhance the applicant's potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria (as applicable for the project proposed).

Scored 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.

The following review criteria are applicable to F31 and F32 applications. For review criteria pertaining to other individual fellowship applications (e.g., F05, F30, F33), please refer to the specific FOA.

Fellowship Applicant: Are the applicant's academic record and research experience of high quality? Does the applicant have the potential to develop as an independent and productive researcher in biomedical, behavioral or clinical science?

Sponsor(s), Collaborator(s), and Consultant(s): Are the sponsor(s) research qualifications (including successful competition for research support) and track record of mentoring appropriate for the proposed fellowship? Are there (1) evidence of a match between the research interests of the applicant and the sponsor (including an understanding of the applicant's research training needs) and (2) a demonstrated ability and commitment of the sponsor to assist in meeting these needs? Are the qualifications of any collaborator(s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed research project?

Research Training Plan: Is the proposed research plan of high scientific quality, and does it relate to the applicant's training plan? Is the training plan consistent with the candidate's stage of research development? Will the research training plan provide the applicant with individualized and supervised experiences that will develop research skills needed for his/her independent and productive research career?

Training Potential: Does the proposed research training plan have the potential to provide the fellow with the requisite individualized and supervised experiences that will develop his/her research skills? Does the proposed research training have the potential to serve as a sound foundation that will lead the fellow to an independent and productive career?

Institutional Environment and Commitment to Training: Are the research facilities, resources (e.g. equipment, laboratory space, computer time, subject populations), and training opportunities adequate and appropriate? Is the institutional environment for the scientific development of the applicant of high quality, and is there appropriate institutional commitment to fostering the fellows' training as an independent and productive researcher?

As applicable for the project proposed, reviewers will consider the following additional terms 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. For additional information, see <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.

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.

Resubmission Applications. When reviewing a resubmission application, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications. When reviewing a renewal application, the committee will consider the progress made in the last funding period.

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/priority score.

Training in the Responsible Conduct of Research. Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address the five Instructional Components (Format, Subject Matter, Faculty Participation, Duration and Frequency of Instruction), as detailed in [NOT-OD-10-019](#). The review of this consideration will be guided by the principles set forth in NOT-OD-10-019. Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE.

Applications from Foreign Organizations. Reviewers will assess whether the research training presents special opportunities and clearly described scientific advantages for the applicant, through the use of talent (e.g., mentor), resources, populations (if applicable), or training environment that are not readily available in the United States or augment existing U.S. talent and/or resources.

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).

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); 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>).

Budget and Period of Support. Reviewers will consider whether the requested period of support is fully justified and reasonable in relation to the proposed fellowship training.

Dual-Level Peer Review

The second level review of Fellowship applications is performed by senior staff of the potential awarding component (Institute, Center, or other unit). Fellowship applications are not required to undergo Advisory Council/Board review.

ARCHIVED

PART II

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

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1. Introduction

A Protection of Human Subjects section of the Research Training Plan is required for all Fellowship applications submitted using the SF424 (R&R) 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 (to help determine whether research that involves the use of human data or biological specimens is human subjects research, refer to this Web site <http://grants.nih.gov/grants/policy/hs>). 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 10, 11, and 12 of the Research Training Plan). All definitions related to human subjects research are linked to text found in [Part III, Section 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.

Do not use the human subjects section to circumvent the page limit of the Research Strategy.

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 1 on the SF424 R&R Other Project Information page. If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

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

Unless you are providing a special justification as described above, no additional information is necessary if no human subjects are involved.

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 1 on the SF424 R&R Other Project Information page and entered your OHRP assurance number in Item 1a. In the Protection of Human Subjects section of the Research Training Plan (Item 9 on the PHS Fellowship Supplemental Form), 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 human subjects 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 1 on the SF424 R&R Other Project Information page, the appropriate exemption number checked in Item 1a, and **NA** entered for the Human Subject Assurance Number since no OHRP assurance number is required for exempt research. In the section on Protection of Human Subjects in the Research Training Plan (Item 9 on the PHS Fellowship Supplemental Form), 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 Training Plan. When in doubt, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services by accessing their Web site <http://www.hhs.gov/ohrp/> for guidance and further information.

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

Please note: If the proposed research involves only the use of human data or biological specimens, you should first determine whether the research involves human subjects. The exemptions do not apply if the research does not involve human subjects. For help determining whether research that involves the use of human data or biological specimens is human subjects research, please refer to this web site <http://grants.nih.gov/grants/policy/hs/>.

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 1 on the SF424 R&R Other Project Information page and entered your OHRP assurance number in Item 1a. In the section on Protection of Human Subjects in the Research Training Plan (Item 9 on the PHS Fellowship Supplemental Form), 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 1 on the SF424 R&R Other Project Information page, entered your OHRP assurance number in Item 1a, and checked **Yes** to Clinical Trial in Item B.7 of the PHS Fellowship Supplemental Form – Research Training Plan.

In the section on Protection of Human Subjects in the Research Training Plan (Item 9 on the PHS Fellowship Supplemental Form), 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 human 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 1 on the SF424 R&R Other Project Information page, entered your OHRP assurance number in Item 1a, and checked **Yes** to Agency-Defined Phase III Clinical Trial in Item 8 on the PHS Fellowship Supplemental Form. In the section on Protection of Human Subjects in the PHS Fellowship Supplemental Form - Research Training Plan (Item 9), 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) the requirements of NIH policy on reporting race and ethnicity data for subjects in clinical Research; and
- 6) additional Requirements for NIH-defined Phase III clinical trials.

See [instructions for Scenario F](#).

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

Scenario A. No Human Subjects Research Proposed

Criteria

Human Subjects Research	No
Exemption Claimed	No
Clinical Trial	N/A
NIH-Defined Phase III Clinical Trial	N/A

Instructions and Required Information

If proposed studies using human data or biological specimens 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. Save this explanation as a .pdf file entitled “Human Subjects Research.pdf” and attach in Item 9 of the PHS Fellowship Supplemental Form – Research Training Plan.

The explanation could include: a description of the source of the data/biological specimens, and whether there is any intervention or interaction with the subjects in order to obtain the specimens and data; what identifiers will be associated; the role(s) of providers of the data/biological specimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be protected.

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 involving the use of coded private information or biological specimens may not constitute human subjects research if the conditions of the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens have been met (<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>).

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

Human Subjects Research	Yes
Exemption Claimed	No
Clinical Trial	No
NIH-Defined Phase III Clinical Trial	No

Instructions and Required Information

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

In the application narrative, provide the required information for each of the following topics below as a separate file. Save each of the four files as a .pdf file and attach in Items 9-12 of the PHS Fellowship Supplemental Form – Research Training Plan.

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

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

Targeted/Planned Enrollment Table(s) - [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

Human Subjects Research	Yes
Exemption Claimed	1, 2, 3, 4, 5, or 6
Clinical Trial	Yes or No
NIH-Defined Phase III Clinical Trial	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, provide the required information for each of the following topics below as a separate file. Save each of the four files as a .pdf file and attach in Items 9-12 of the PHS Fellowship Supplemental Form – Research Training Plan.

Protections for Human Subjects – Include the following statement: ‘This Human Subjects Research falls under Exemption(s)’ Clearly identify which exemption(s) (1, 2, 3, 4*, 5, 6) you are claiming, and justify why the research meets the criteria for exemption 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(s) - [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

Human Subjects Research	Yes
Exemption	Yes or No
Clinical Trial	Yes or No
NIH-Defined Phase III Clinical Trial	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 cannot be fully described, 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 Training 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. For clinical research, 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 Training Plan.

Under no circumstance may human subjects be involved in research until approval is granted by the awarding entity, and certification of IRB approval has been accepted by the agency.

In the application narrative, provide the required information for each of the following topics below as a separate file. Save each of the four files as a .pdf file and attach in Items 9-12 of the PHS Fellowship Supplemental Form – Research Training Plan. 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](#). If the research will include a clinical trial, even if exempt, include a Data and Safety Monitoring Plan as described in [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(s) - [Section 4.3](#)

Inclusion of Children - [Section 4.4](#)

Scenario E: Clinical Trial

Criteria

Human Subjects Research	Yes
Exemption	Yes or No
Clinical Trial	Yes
NIH-Defined Phase III Clinical Trial	No

Instructions and Required Information

In the application narrative, provide the required information for each of the following topics below as a separate file. Save each of the four files as a .pdf file and attach in Items 9-12 of the PHS Fellowship Supplemental Form – Research Training Plan.

Protection of Human Subjects - [Section 4.1 - 4.1.6](#)

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

Targeted/Planned Enrollment Table(s) - [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

[Human Subjects Research:](#)

Yes

[Exempt:](#)

No

[Clinical Trial:](#)

Yes

[NIH-Defined Phase III Clinical Trial:](#)

Yes

Instructions and Required Information

In the application narrative, provide the required information for each of the following topics below as a separate file. Save each of the four files as a .pdf file and attach in Items 9-12 of the PHS Fellowship Supplemental Form – Research Training Plan.

Protection of Human Subjects - [Section 4.1 - 4.1.6](#). Also include the statement that ‘This Human Subjects Research involves an NIH-Defined Phase III Clinical Trial.’

Inclusion of Women and Minorities - [Section 4.2 - 4.2.1](#)

Targeted/Planned Enrollment Table(s) - [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

On the PHS Fellowship Supplemental Form – Research Training Plan, include attachments for Items 9 through 12, if required. 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, and Design**

- Describe the proposed involvement of human subjects in the work outlined in the Research Strategy section.
- Describe and justify the characteristics of the subject population, including their anticipated number, age range, and health status if relevant.
- Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special vulnerable populations, 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.
- If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention's dose, frequency, and administration.
- 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. Explain how data from the site(s) will be obtained, managed, and protected.

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, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information 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 human 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 clinical trials 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 Training 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 proposed 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 Web sites for more information related to IND and IDE requirements:
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 (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. Fellowship applicant (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 need 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. For additional guidance on creating this Plan, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>.

4.1.6 ClinicalTrials.gov Requirements

[Public Law 110-85](#) (also known as the FDA Amendments Act (FDAAA) of 2007) 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 clinical trials whether required under the law or not.

Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Web site (<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 applicable clinical trials which require registration and results reporting under FDAAA, provide the NCT number/s, Brief Title/s (protocol title intended for the lay public – see [Definitions](#)), and the identity (name, organization, and e-mail address—required for internal administrative use only) of the responsible party (or parties) in the human subjects section of the Research Plan under a section heading entitled ClinicalTrials.gov. If a new applicable clinical trial is proposed, under the heading ClinicalTrials.gov, provide a clear statement in the human subjects section of the Research Plan that the application includes an applicable clinical trial which requires registration in ClinicalTrials.gov.

The entity responsible for registering the trial 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://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3>), 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). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

For the complete statutory definitions of “responsible party” and “applicable clinical trial”, refer to [Elaboration of Definitions of Responsible Party and Applicable Clinical Trial](#).

The signature on the application of the Authorized Organizational Representative assures compliance with FDAAA.

Additional information can be found on the ClinicalTrials.gov web site

(http://grants.nih.gov/ClinicalTrials_fdaaa).

4.2 Inclusion of Women and Minorities

In the attachment for Item 10, include a heading entitled “Inclusion of Women and Minorities.” 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 inclusion of women and minorities in clinical research.

In this section of the Research Training 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 cannot be described (item 3 below). Alternatively, describe the gender and minority composition of the population base from whom the specimens and/or data will be obtained. Include the Targeted/Planned Enrollment Tables 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.

Below are examples of acceptable justifications for the 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 among subgroups.

4.3 Instructions for Completing the Targeted/Planned Enrollment Tables for Reporting Race and Ethnicity Data for Subjects in Clinical Research

If your application includes Targeted/Planned Enrollment tables, save all as a single PDF file and attach them in Item 11. Targeted/Planned Enrollment of the PHS Fellowship Supplemental Form – Research Training Plan.

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/424/SF424R-R_enrollmentreport.doc) 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

(http://grants.nih.gov/grants/funding/424/SF424R-R_enrollment.doc)

Attach the Targeted/Planned Enrollment Table as Item 11. 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 Tables. 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 Targeted/Planned Enrollment Tables that describe research in foreign sites, investigators should asterisk and footnote the table indicating that data include 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/424/SF424R-R_enrollmentreport.doc) must be used for reporting accrual data to the NIH. For Revision applications, any proposed additions to the Targeted/Planned Enrollment Tables 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 must 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 12 of the Research Training 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 working 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 proposed 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 apply:

1. The research topic to be studied is not relevant to children.
2. Laws or regulations bar 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/Center 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 Research 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 all organizations engaged in nonexempt human subjects research supported or conducted by the DHHS 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. In general, OHRP considers organizations that receive direct support from DHHS for the conduct of nonexempt human subjects research to be engaged in human subjects research (for more information on whether an institution is engaged in human subjects research, refer to: <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>). When a research project is conducted by multiple organizations, each organization that is engaged in nonexempt human subjects research must hold an FWA and comply with the regulations at 45 CFR 46.

Nonexempt research involving human subjects may only be conducted under a DHHS award if the engaged organization(s) 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 an application not being reviewed. 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 Training 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/cfcr/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 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 Web site 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 subjects who become prisoners after the research has started) 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 Web site (<http://www.hhs.gov/ohrp/policy/index.html>).

[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 under the institutional assurance 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.

According to OHRP policy, in general, an institution is 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/guidance/engage08.html>. 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 Web site at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

DHHS human subject regulations at 45CFR46.103(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. For multi-site research, the primary grantee is expected to collect the certification from each subrecipient.

Any modifications to the Research Training 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 Fellow 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 involving human subjects. For information relating to this requirement, see the following notices <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html>, <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. 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 and provide guidance or can be modified to provide training in this area. See <http://phrp.nihtraining.com> 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 funding IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances must be designated 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 Training 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.

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) in 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). 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.

See NIH Policy on [Inclusion of Women and Minorities](#) and http://grants.nih.gov/grants/funding/women_min/women_min.htm.

5.9 Research on Transplantation of Human Fetal Tissue

In checking the “I agree” box on line 18 of the SF424 (R&R) Cover component, 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

By checking the “I agree” box on line 17 of the SF424 (R&R) Cover component, the Authorized Organizational Representative of the applicant organization certifies that if research using human embryonic stem cells (hESCs) is proposed, the applicant organization will identify hESCs to be used from the NIH Registry (<http://stemcells.nih.gov/research/registry/>), or, if a specific cell line cannot be referenced at the time of application, certify that one from the NIH Registry will be used, in accord with the NIH Guidelines on Human Stem Cell Research (<http://stemcells.nih.gov/policy/2009guidelines.htm>). 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 checking the “I agree” box on line 17 of the SF424 (R&R) Cover component, the Authorized Organizational Representative of the applicant organization certifies that if the research includes 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**

ARCHIVED

1. Policy

1.1 (Reserved)

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 NIH Institutes and Centers 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 applications 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 activity code (e.g., R01) is to be submitted for a different grant activity code (e.g., 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 Individual Fellowship applications submitted for the April 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 April 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.

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. Fellows and their sponsoring institutions need to exercise their best judgment in determining the advisability of a Resubmission application after several years have elapsed.

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 (Reserved)

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(s) in an administrative note, and will not normally include their assessment in the overall impact 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 and the NIH Final Policy on Sharing Research Data, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

1.5.2 Sharing Model Organisms

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 Web site 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

According to NIH Grants Policy and Federal law, NIH recipient organizations must promptly report all inventions that are either conceived or first actually reduced to practice using NIH 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 Drive, 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 for fellowship applicants includes:

- Certifications:
 - If human subjects are involved, provide the Federal-wide Assurance number (if not previously provided) and the Certification of IRB Review and Approval of the research proposed in the application, and any IRB imposed changes. Pending or out-of-date approvals are not acceptable. IRB approval must be dated within the last year to be valid. See [Part II.5.4 IRB Approval](#) for more information.
 - If vertebrate animals are involved, provide the Animal Welfare Assurance number of the applicant organization (if not previously provided), date of IACUC approval of the research proposed in the application, and any IACUC-imposed changes. Pending or out-of-date approvals are not acceptable. IACUC approval must be dated within the last three years to be valid. See [Part III Section 2.2 Vertebrate Animals](#).
 - Human Subjects Education: For grants involving Human Subjects, provide certification that each person identified under 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. See [Required Education in the Protection of Human Research Participants](#) in Part II Section 5.5.
- Human Subject Assurance Number: For a temporary period of time, applicants who checked Yes to the question *If no, is the IRB review Pending* on the Other Project Information form should provide the appropriate Federal Wide Assurance number as a Just-in-Time submission.

Applicants are advised to submit this information (countersigned by an authorized business official) only when requested by the awarding component. Guidance for submitting this information will be provided at the time of the request. Alternatively, this information may 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 (Reserved)

1.9 (Reserved)

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

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 Library of Medicine's (NLM) PubMed Central (PMC), 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 application, proposals, and progress reports that fall under the Policy, were authored or co-authored by the applicant and arose from the NIH support must include the PubMed Central reference number (PMCID) or NIH Manuscript Submission 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 activity codes, 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 NIH Plans to Transition to the SF424 (R&R) Application and Electronic Submission through Grants.gov

As first announced in May 2008 (See [NOT-OD-08-073](#)), NIH transitioned the Individual Fellowship application from the PHS 416-1 application to the SF424 (R&R) application and electronic submission through Grants.gov. The transition to electronic submission is being done by activity code. Applicants should refer to the Timeline to determine when a particular activity code has transitioned, or will transition, 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.

For more information on NIH's transition plans, see the Web site for Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>.

1.14 (Reserved)

1.15 (Reserved)

1.16 Policy on Instruction in the Responsible Conduct of Research

NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. These mechanisms include: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2, and U2R. This policy also applies to any other NIH-funded programs supporting research training, career development, or research education that require instruction in responsible conduct of research as stated in the relevant FOA.

A. Instructional Components

NIH recognizes that instruction in responsible conduct of research occurs formally and informally in educational settings and that informal instruction occurs throughout the research training experience. The guidance provided below is directed at formal instruction in responsible conduct of research and describes the accumulated experiences and the best practices of the scientific community over the past two decades.

1. **Format:** Substantial face-to-face discussions among the participating trainees/fellows/scholars/participants; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs (see below), or unusual and well-justified circumstances.

2. **Subject Matter:** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:
- conflict of interest – personal, professional, and financial
 - policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
 - mentor/mentee responsibilities and relationships
 - collaborative research including collaborations with industry
 - peer review
 - data acquisition and laboratory tools; management, sharing and ownership
 - research misconduct and policies for handling misconduct
 - responsible authorship and publication
 - the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all of the above topics.

3. **Faculty Participation:** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.
4. **Duration of Instruction:** Instruction should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.
5. **Frequency of Instruction:** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual fellows/scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in responsible conduct of research at least once during this career stage. Senior fellows and career award recipients (including F33, K02, K05, and K24 awardees) may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate

circumstances, in a year when the trainee, fellow or career award recipient is not actually supported by an NIH grant. This instruction can be documented as described below.

B. Special Considerations by Type of Award

Short-term training and research education programs (for example, T35 and R25 programs lasting six or fewer months, short-term trainees supported on T15, T32 and T34 programs, and short-term participants in R25 programs): The duration of RCR instruction within short-term institutional programs should be appropriate for the total duration of the program and should be justified in the application and is an instance where on-line instruction could be appropriate. Such programs may also use innovative strategies to incorporate instruction in responsible conduct of research and to relate instruction in responsible conduct of research to the scientific focus of the short-term program.

Individual awards: In keeping with the individual nature of these programs, fellows and scholars, along with their institutions and sponsors/mentors, are encouraged to tailor instruction in responsible conduct of research to the needs of the individual. Thus, instruction may go beyond formal institutional courses and provide opportunities for the individual to develop their own scholarly understanding of the ethical issues associated with their research activities and their impact on society. An individualized plan would be appropriate in the rare instances where an institution does not have an established formal mechanism for such instruction.

Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process or not reviewed.

Additional information, including resources on Instruction in Responsible Conduct of Research, can be found in [NOT-OD-10-019](#).

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2. Assurances and Certifications

Each application to the PHS requires that the following assurances and certifications be verified by checking the “I agree” box on line 17 of the SF424 (R&R) Cover Component.

Fellowship Applicant (PD/PI) and SO Verification

After the Fellowship Applicant (PD/PI) and SO successfully submit an application, they will receive an automatically generated email requesting them to view and verify (or reject) the application on-line in the Commons. To do this, the PD/PI and SO need to:

1. Make sure they can log onto the NIH eRA Commons. Before they receive the email, they should be sure to know their Commons account names and passwords.
2. Verify the electronic grant application via the NIH eRA Commons. Complete instructions on the verification process are in the Applicant Package.

The assurances listed and explained below may or may not be applicable to your project, program, or type of applicant organization. Applicants and grantees must comply with a number of additional public policy requirements. Refer to the *NIH Grants Policy Statement* for additional information. A copy of the NIH Grants Policy Statement (<http://grants.nih.gov/grants/policy/policy.htm>) for additional information.

2.1 Human Subjects Research

(See also [Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Training 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 all organizations engaged in non-exempt human subjects research supported or conducted by the DHHS 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. In general OHRP considers organizations that receive direct support from DHHS for the conduct of nonexempt human subjects research to be engaged in human subjects research (for more information on whether an institution is engaged in human subjects research, refer to <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>). When a research project is conducted by multiple organizations each organization that is engaged in human subjects research must hold an FWA and comply with the regulations at 45 CFR 46.

Non-exempt research involving human subjects may only be conducted under a DHHS award if the engaged organization(s) 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.

Research involving the use of coded private information or biological specimens may not constitute human subjects research. Refer to the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens to clarify when such research is or is not research involving human subjects (available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>). For additional help determining whether research that involves the use of human data or biological specimens is human subjects research, please refer to this web site: <http://grants.nih.gov/grants/policy/hs/>.

Vulnerable Populations

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners (including subjects who become prisoners after the research has started), 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 Web site (<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-08-054.html>, <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. 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, curricula are available and provide guidance or can be modified to provide training in this area. See <http://phrp.nihtraining.com/users/login.php> 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 checking the “I agree” box on line 17 of the SF424 (R&R) Cover Component, 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

By checking the “I agree” box on line 17 of the SF424 (R&R) Cover component, the Authorized Organizational Representative of the applicant organization certifies that if research using human embryonic stem cells (hESCs) is proposed, the applicant organization will identify hESCs to be used from the NIH Registry (<http://stemcells.nih.gov/research/registry/>), or, if a specific cell line cannot be referenced at the time of application, certify that one from the NIH Registry will be used, in accord with the NIH Guidelines on Human Stem Cell Research (<http://stemcells.nih.gov/policy/2009guidelines.htm>). The AOR further certifies that the hESCs will be used in accordance with any restrictions associated with the line as cited on the Registry (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-029.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 Training Plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide the 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.

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 checking the “I agree” box on line 17 of the SF424 (R&R) Cover Component, 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). 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.

The entity responsible for registering the trial is the “responsible party.”

For the complete statutory definitions of “responsible party” and “applicable clinical trial,” refer to [Elaboration of Definitions of Responsible Party and Applicable Clinical Trial](#).

Additional information can be found on the ClinicalTrials.gov web site (http://grants.nih.gov/ClinicalTrials_fdaaa/).

2.2 Vertebrate Animals

NIH no longer requires Institutional Animal Care and Use Committee (IACUC) approval of the proposed research **before NIH peer review** of an application (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html>).

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

The PHS *Policy on Humane Care and Use of Laboratory Animals* requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The

PHS policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable state or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163.

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

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

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 45 CFR 76, “Government-wide Debarment and Suspension (Nonprocurement).” Changes in this Government-wide requirement (adopted in the November 26, 2003 Federal Register Notice) now implement this as a term and condition of an award. For Kirschstein-NRSA Individual Fellowships, this policy applies to the individual applicant as well as the sponsoring institution.

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

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 at <http://www.whitehouse.gov/omb/grants/sfillin.pdf> and from GrantsInfo, National Institutes of Health, email: GrantsInfo@nih.gov, (301) 435-0714.

Prohibition on Awards to 501(c)4 Organizations That Lobby

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

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.”

In checking the “I agree” box on line 18 of the SF424 (R&R) Cover Component, the Authorized Organizational Representative of the applicant organization certifies that:

1. The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;
2. The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;
3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

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. Department of Health and Human Services
Office of Research Integrity
1101 Wootton Parkway, Suite 750
Rockville, MD 20852
AskORI@osophs.dhhs.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 HHS 690) with Title VI of the Civil Rights Act of 1964 (P.L. 88352, as amended), which prohibits discrimination on the basis of race, color, or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (P.L.

92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (P.L. 94-135), which prohibits discrimination on the basis of age.

The Assurance of Compliance Form HHS 690 is available from <http://www.hhs.gov/forms/HHS690.pdf>.

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

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*. Further, the *NIH Guidelines* include special review and reporting requirements for the conduct of human gene transfer studies (under Appendix M). Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of NIH funds for recombinant DNA research at the organization or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization. A copy of the *NIH Guidelines* is posted at the following URL: http://oba.od.nih.gov/rdna/nih_guidelines_oba.html and may be obtained from the NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838.

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.

In checking the “I agree” box on line 18 of the SF424 (R&R) Cover Component, the Authorized Organizational Representative of the applicant organization certifies 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 through the FCOI module in the eRA Commons 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

BAN ON FUNDING OF HUMAN EMBRYO RESEARCH (Section 509)

This section continues the current ban that prohibits NIH from using appropriated funds to support human embryo research. Grant, cooperative agreement, and contract funds may not be used for: “(a)...(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term ‘human embryo or embryos’ includes any organism not protected as a human subject under [45 CFR Part 46](#) as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.”

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

LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES (Section 510)

“(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C.812). (b)The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally sponsored clinical trials are being conducted to determine therapeutic advantage.”

RESTRICTION ON DISTRIBUTION OF STERILE NEEDLES (Section 505)

“None of the funds contained in this Act may be used to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by the local public health or local law enforcement authorities to be inappropriate for such distribution.”

RESTRICTION ON ABORTIONS (Section 507)

“(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.”

(b) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion.

(c) The term “health benefits coverage” means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.”

EXCEPTION TO RESTRICTION ON ABORTIONS (Section 508)

“(a) The limitations established in the preceding section shall not apply to an abortion—

- (1) if the pregnancy is the result of an act of rape or incest; or
- (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State’s or locality’s contribution of Medicaid matching funds).

(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State’s or locality’s contribution of Medicaid matching funds).

(d) (1) None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

(2) In this subsection, the term “health care entity” includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

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/docs/42cfr73.pdf>>, Select Agents and Toxins.

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

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 Web sites maintained by NIH, CDC, and USDA:

NIH Office of Extramural Research Select Agent Information:

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/

2.14 Fellow and Sponsor Assurance

It is a compliance requirement that the applicant organization must secure and retain a written assurance from the Fellow and Sponsor 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 HHS 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 Fellow's and Sponsor's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Fellow and Sponsor to criminal, civil, or administrative penalties; (3) that the Sponsor will provide appropriate training, adequate facilities, and supervision if a grant is awarded as a result of the application; (4) that the Fellow has read the Ruth L. Kirschstein National Research Service Award Payback Assurance (See link below, section I. Service Requirement) and will abide by the Assurance if an award is made; and (5) that the award will not support residency training.

Other helpful links:

Guide Notice for Payback Obligation: <http://grants.nih.gov/grants/guide/notice-files/not93-201.html>

Full Payback Agreement: <http://grants.nih.gov/grants/funding/416/phs6031.doc>

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. In addition, NIH has determined that most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous waste, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

This requirement is in addition to 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.

2.16 (Reserved)

2.17 Kirschstein-NRSA Payback Assurance

This is applicable ONLY to the F32 (postdoctoral fellows) and F33 (senior fellows).

Section 487 of the Public Health Service Act, as amended (42 USC 288), and implementing regulations (42 CFR Part 66) require satisfactory assurance from a prospective recipient of a Kirschstein-NRSA Individual Fellowship that, in the first 12 months of Kirschstein-NRSA postdoctoral support, he or she will meet the following service requirement. Kirschstein-NRSA predoctoral fellows or other fellows who

have already had 12 months of Kirschstein-NRSA postdoctoral support do not incur a service payback obligation.

Kirschstein-NRSA Individual Fellowships will be governed by the service payback requirements articulated in the National Research Service Award Guidelines for Individual Awards and Institutional Grants. These guidelines can be found in the NRSA portion of the most recent version of the NIH Grants Policy Statement found at: <http://grants.nih.gov/grants/policy/policy.htm#gps>. Applicants accepting an approved Kirschstein-NRSA Individual Fellowship agree to the following assurance:

I. Service Requirement - In accepting a Ruth L. Kirschstein National Research Service Award to support my postdoctoral research training, I understand that my first 12 months of Kirschstein-NRSA Individual Fellowship support for postdoctoral research training carry with it a payback obligation. I hereby agree to engage in a month of health-related research, health-related research training, health-related teaching, and/or health-related activities for each month I receive a Kirschstein-NRSA Individual Fellowship for postdoctoral research training up to and including 12 months. If I receive a Kirschstein-NRSA Individual Fellowship for postdoctoral research training for more than 12 months, I agree that the 13th month and each subsequent month of Kirschstein-NRSA-supported postdoctoral research training will satisfy a month of my payback obligation incurred in the first 12 months. This service shall be initiated within 2 years after the end of Kirschstein-NRSA support. The health-related research, teaching, and/or activities shall be on a continuous basis and shall average more than 20 hours per week of a full work year.

II. Financial Payback Provisions - I understand that if I fail to undertake or perform such service in accordance with Section I above, the United States will be entitled to recover from me an amount determined in accordance with the following formula:

$$A = F [(t-s)/t]$$

where "A" is the amount the United States is entitled to recover; "F" is the sum of the total amount paid to me under the initial 12 months of my postdoctoral Ruth L. Kirschstein National Research Service Award support; "t" is the total number of months in my service obligation; and "s" is the number of months of such obligation served.

Except as provided in Section III below, any amount the United States is entitled to recover from me shall be paid within the 3-year period beginning on the date the United States becomes entitled to recover such amount. The United States becomes entitled to recover such amount 2 years after termination of my Ruth L. Kirschstein National Research Service Award support if I do not engage in acceptable service payback activities in accordance with Section I. If I elect to engage in financial repayment before the end of the 2-year period, the United States becomes entitled to recover such amount on the date of my election. Interest on the amount begins on the date the United States becomes entitled to recover such amount and is at the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates prevailing on that date. I understand that I will be allowed an initial 30-day interest-free period in which to fully pay such amount, and that I may prepay any outstanding balance after that period to avoid additional interest. I further understand that I will be subject to authorized debt collection action(s) (including any accrued interest and late fees) should I fail to comply with the payback provisions of this Section II.

III. Conditions for Break in Service, Waiver, and Cancellation - I hereby understand that the Secretary of Health and Human Services:

- A. May extend the period for undertaking service, permit breaks in service, or extend the period for repayment, if it is determined that:
 1. Such an extension or break in service is necessary to complete my clinical training or to participate in a NIH Loan Repayment Program;
 2. Completion would be impossible because of temporary disability; or

3. Completion would involve a substantial hardship and failure to extend such period would be against equity and good conscience;
- B. May waive my obligation, in whole or in part, if it is determined that:
1. Fulfillment would be impossible because I have been permanently or totally disabled; or
 2. Fulfillment would involve a substantial hardship and the enforcement of such obligation would be against equity and good conscience;
- C. Will, in the event of my death, cancel any obligation incurred under this payback agreement.

IV. Termination Notice-Annual Report of Employment-Change of Address and/or Name - I agree to complete and submit a termination notice immediately upon completion of support. Thereafter, on an annual basis I agree to complete and submit all Payback Activities Certification forms sent to me by the National Institutes of Health or the Agency for Healthcare Research and Quality concerning post-award activities, and agree to keep those agencies advised of any change of address and/or name until such time as my total obligation is fulfilled.

V. Program Evaluation - I understand that I also may be contacted from time to time, but no more frequently than once every 2 years, after the end of this award to determine how the training obtained has influenced my career. Any information thus obtained would be used only for statistical purposes and would not identify me individually.

VI. Certification - By signing the certification block on the application form, I certify that I have read and understood the requirements and provisions of this assurance and that I will abide by them if an award is made.

ARCHIVED

3. Definitions

Activity Code. A 3-character code used to identify a specific category of extramural research activity, applied to various funding activity codes. NIH uses three funding activity codes for extramural research awards: grants, cooperative agreements and contracts. Within each funding activity code, NIH uses 3-character activity codes (e.g., F32, K08, P01, R01, T32, etc.). to differentiate the wide variety of research-related programs NIH supports. A comprehensive list of activity codes is on the NIH Web site at http://grants.nih.gov/grants/funding/ac_search_results.htm.

AHRQ. Agency for Healthcare Research and Quality, which is a component of HHS.

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

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

Applicant Organization Types.

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

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

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

Nonprofit: An institution, corporation, or other legal entity no part of whose net earnings may lawfully inure to the benefit of any private shareholder or individual.

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

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

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, and is organized for profit.
2. Is at least 51% owned 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.

CFR. Code of Federal Regulations.

Clinical Research. See [Human Subjects Research Definitions and Terms](#).

Coded. See [Human Subjects Research Definitions and Terms](#).

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.

Foreign Component. A foreign component of a grant to a U.S. institution is defined as a component of a grant to an U.S. organization that provides support to any significant element or segment of the project to be performed outside the U.S. (including the involvement of human subjects or laboratory animals; extensive foreign travel for the purpose of data collection, surveying, sampling, and similar activities; and any activity of the recipient that may involve the population, environment, resources, or affairs of a foreign country), either by the recipient’s project staff or individuals employed by a foreign organization (for example, under a contract or a consortium agreement). Foreign travel for consultation is not considered a foreign component.

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.

HHS. U.S. Department of Health and Human Services.

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 studies, 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. For the purpose of the Guidelines 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:

- (1) 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
- (2) 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 for 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 Web site 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. Note: It is uncommon for investigators applying for an NIH grant to qualify for this exemption. Please seek

guidance from the relevant NIH IC or from the OER Human Subject Protection staff if you think your project is eligible for Exemption 5.

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: male and female. 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*

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 Guidance on Research Involving Coded Private Information on Biological Specimens: <http://www.hhs.gov/humansubjects/guidance/cdebiol.pdf>.)

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 general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:

- (a) observing or recording private behavior;
- (b) using studying, or analyzing for research purposes identifiable private information or identifiable specimens provided to investigators from any source; and
- (c) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

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.

IC. An Institute or Center of the National Institutes of Health.

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 Animal Care and Use Committee (IACUC). An administrative body established to oversee the institution’s animal program, facilities and research activities.

Institutional Review Board (IRB). An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities.

Mechanisms. Extramural research awards are divided into three main funding activity mechanisms: grants, cooperative agreements and contracts. A funding mechanism is the type of funded application or transaction used at the NIH. Programs are areas within the funding mechanisms. Activity codes identify categories applied to the various funding mechanisms. Also known as award mechanism or support mechanism.

NRSA Individual Fellowship. Ruth L. Kirschstein National Research Service Award provided to individuals for research training in biomedical and behavioral research.

OHRP. Office for Human Research Protections.

OLAW. Office of Laboratory Animal Welfare.

Payback. Requirement that the recipient of a NRSA postdoctoral fellowship engage in qualified research or teaching activities for a length of time equal to the period of NRSA support received. Only the first year of training incurs a payback obligation. In general, payback activity must involve at least 20 hours per week and be conducted over 12 consecutive months; special exceptions may be considered on a case-by-case basis.

Postdoctoral Scholar. An individual who has received a doctoral degree (or equivalent) and is engaged in a temporary and defined period of mentored advanced training to enhance the professional skills and research independence needed to pursue his or her chosen career path.

Program Director/Principal Investigator (PD/PI). The PD/PI is the individual responsible for the overall scientific and technical direction of the project. For a Fellowship application or Fellowship award the “Fellow” is considered the PD/PI.

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.

Scientific Review Group (SRG). The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. The primary function is the review and rating of research grant applications for scientific and technical merit.

Scientific Review Officer (SRO). A Federal scientist who presides over a Scientific Review Group (SRG) and is responsible for coordination and reporting the review of each application assigned to it.

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 are requested under the grant.

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 and those with a postdoctoral role 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 or compensation 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).

Sponsor/Co-Sponsor. One or more designated individual(s) responsible for providing the applicant with research training and career guidance throughout the grant award period.

Sponsoring Institution. Institution legally responsible for committing facilities for the Kirschstein-NRSA Individual Fellowship applicant and financially responsible for the use and disposition of fellowship funds.

Stipend. A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

Summary Statement. A combination of the reviewers' written comments and the SRO's summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

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.

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4. General Information

4.1 Research Training Grant Activity Codes

The following table summarizes the Training and Career Development Program mechanisms NIH uses. For more detailed information, visit the OER Web site

http://grants.nih.gov/grants/funding/funding_program.htm.

Training, Fellowships and Career Development Programs

TYPE (ACTIVITY CODE)	DESCRIPTION
<p>Institutional Research Training including Ruth L. Kirschstein National Research Service Award (T32/ T34/T35) http://grants.nih.gov/training/nrsa.htm</p>	<p>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.</p>
<p>Individual Ruth L. Kirschstein National Research Service Award Fellowships (NRSA: F30/F31/F32/F33) http://grants.nih.gov/training/nrsa.htm</p>	<p>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.</p>
<p>Career Development Award (K Award) http://grants.nih.gov/training/careerdevelopmentawards.htm</p>	<p>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.</p>

4.2 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 PHS requests the last four digits of the Social Security Number under Section 301(1) and 487 of the PHS Act as amended (42 U.S.C. 241a and U.S.C. 288). Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this section of the Social Security Number. All analyses conducted on the date of birth, gender, race, and/or ethnic origin data will report aggregate statistical findings only and will not identify individuals. If you decline to provide this information, it will in no way affect consideration of your application.

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.

4.3 Information Available to the PD/PI(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.

4.4 Information Available to the General Public

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee institution, the PD/PI, and the amount of the award. The Project Summary/Abstract, from Item 6 on the Other Project Information Component, of a funded research grant application is sent to the National Technical Information Service (NTIS), U.S. Department of Commerce, where the information is used for the dissemination of scientific information and for scientific classification and program analysis purposes. These descriptions are available to the public from the NTIS.

NIH also routinely places information about awarded grants, including project title, name of the PD/PI, and project description (abstract) in the [RePORTER](#) system.

Freedom of Information Act Requirements

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants upon request, regardless of the intended use of the information. Generally available for release, upon request are: all funded grant applications and progress reports **including** their derivative funded **noncompeting supplemental** grant progress reports; pending and funded **noncompeting continuation** progress reports; progress reports of grantees; and final reports of

any review or evaluation of grantee performance conducted or caused to be conducted by the DHHS. Generally **not** available for release to the public are: **competing** grant progress reports (new, resubmission, renewal, and revisions) 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 PD/PI 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.

4.5 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.