

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)

Forms Version C application packages

Updated November 25, 2014

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PARTI

Instructions for Preparing and Submitting an Application

Foreword

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

This application guide includes changes to the SF424 Research & Related (R&R) form C instructions necessitated by the OMB renewal and Grants.gov's subsequent release of updated forms in June 2013. Changes have also been made to various PHS 398 forms and instructions approved by OMB in August 2012 and released by Grants.gov in June 2013. Parts II (Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan) and III (Policies, Assurances, Definitions, and Other Information) of the previous version of the application guide have been moved to a stand-alone document titled, "Supplemental Grant Application Instructions."

Modifications include the following:

SF424 (R&R) Forms

System for Award Management (SAM) Registration

• A change from the requirement to register with the Central Contractor Registry Database (CCR) to the System for Award Management (SAM).

SF 424 (R&R) Form

- A name change, previously the SF 424 (R&R) Cover Form
- A new field for the "Previous Grants.gov Tracking ID" is included. Form behavior will be adjusted so that applications with Submission Type of "Change/Corrected Application" require an entry in the "Previous Grants.gov Tracking ID" field rather than requiring an entry in the "Federal Identifier" field.
- A new "Cover Letter Attachment" has been added and a separate PHS Cover Letter form
 will no longer be used. However, NIH will continue to keep the Cover Letter separate from
 the assembled application image and available only to authorized staff.

PHS 398 Forms

• The Fellowship Reference Form will no longer be used. Reference letters will be submitted through the eRA Commons using the SF424 (R&R) Form with a Cover Letter attachment and will not require a specific form.

Planned Enrollment Report Form & Cumulative Inclusion Enrollment Report Form

 Added optional inclusion forms in application packages to allow for the collection as discrete data rather than .pdf attachments.

This application guide is used as a companion document to the SF424 Research and Related (R&R) application forms. In addition to the SF424 (R&R) forms, applications to NIH and AHRQ will include agency-specific forms in the "PHS Fellowship Supplemental Form," as approved and cleared by the PHS 416 (OMB No. 0925-0002). These PHS Fellowship forms were developed to

continue the collection of agency-specific data required for a complete application. While these agency-specific forms 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) forms. A complete application to NIH and AHRQ will include SF424 (R&R) forms and PHS Fellowship forms. Instructions for all application forms, SF424 (R&R) and "PHS Fellowship Supplemental Form", are found in this document.

The use of these 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 SF424 (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 website 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:

<u>Part I</u>: Instructions for Preparing and Submitting the Application. Part I includes specific instructions for completing the application forms as well as information on electronically submitting applications through Grants.gov.

Parts II and III are incorporated into this application guide by reference. They are in a separate document titled, "Supplemental Instructions."

<u>Part II</u>: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. Part II is to be used if your proposed research will involve human subjects. These instructions assist in determining whether human subjects are involved and include scenarios and detailed instructions for completing the PHS 398 Research Plan form.

<u>Part III</u>: **Policies, Assurances, 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 <u>NIH Grants Policy Statement</u> applies to all NIH awardees; other PHS agencies (including AHRQ) use the <u>HHS Grants Policy Statement</u>.

1.2 NIH and AHRQ Extramural Research and Research Training Programs

The NIH Office of Extramural Research Grants homepage (http://grants.nih.gov/grants/oer.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 e-mailing 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 http://www.ahrq.gov/funding/training-grants/rsrchtng.html.

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 award Kirschstein-NRSA fellowships. Fogarty International Center (FIC) and National Library of Medicine (NLM) also 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 these types of award are strongly encouraged to consult with the appropriate NIH IC and AHRQ staff before submitting an application. (For example, Postdoctoral (F32) fellowships are provided by the NIH ICs and AHRQ. AHRQ does not provide senior fellowships (F33). Specific FOAs should always should be consulted for guidance.

Staff contact information can be found in each Funding Opportunity Announcement (FOA) published as a Program Announcement (PA) or Request for Applications (RFA) and below in the Interactions with NIH and AHRQ Staff section.

For more information, see the <u>NIH Research Training and Career Development website</u> and the AHRQ Research Training website.

A partial list of fellowship activity codes and programs are provided below. As noted in the descriptions in Supplemental Instructions 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 website 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 **strongly encouraged** to communicate with NIH and AHRQ staff throughout the entire application, review and award process. Web site addresses and staff 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 are encouraged to check this Web site for current contact information

[Table 1.4-1. PHS Agency Contact Table]

PHS AGENCY (LINK TO WEBSITE)	AWARDING COMPONENT (LINK TO WEBSITE)	TELEPHONE NUMBER
National Institutes of	Eunice Kennedy Shriver National Institute of Child	301-496-0104
Health (NIH)	Health and Human Development	
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 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
NIH	National Institute of Biomedical Imaging and Bioen- gineering	301-451-4792
NIH	National Institute on Deafness and Other Com- munication Disorders	301-496-1804
NIH	National Institute of Dental and Craniofacial Research	301-594-4800
NIH	National Institute of Diabetes and Digestive and Kidney <u>Diseases</u>	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 on Minority Health and Health Disparities	301-402-1366
NIH	National Institute of Neurological Disorders and Stroke	301-496-9248
NIH	National Institute of Nursing Research	301-594-6906

PHS AGENCY (LINK TO WEBSITE)	AWARDING COMPONENT (LINK TO WEBSITE)	TELEPHONE NUMBER
NIH	National Library of Medicine	301-496-4621
NIH	Center For Scientific Review	301-435-0715
Agency for Healthcare Research and Quality	Agency for Healthcare Research and Quality	301-427-1447

Before Submission

Applicants are strongly encouraged to contact NIH or AHRQ staff with their questions before submitting an application.

Contact <u>GrantsInfo</u> and/or the <u>Division of Receipt and Referral, Center for Scientific Review</u> (CSR), NIH:

- To identify Institutes/Centers (ICs) at NIH, AHRQ and/or a Scientific Review Group (SRG) that might be appropriate for your application. Note: requests for assignment to an Institute/Center and/or an SRG may be made in the SF424 (R&R) Form in the Cover Letter attachment 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 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.

Communications from the Division of Receipt and Referral (DRR) are accessible to applicants and applicant organizations in the eRA Commons in a new "Correspondence" section of the Commons detailed status screen for the application. Applicants will be notified by email to check their Commons account. DRR will notify an applicant when: 1) additional information is required before her/his application can be assigned to a scientific review group (SRG) and NIH Institute or Center (IC) for funding consideration; 2) an applicant's request for an IC assignment cannot be honored; or 3) it has been determined that the application does not comply with NIH policy. For additional information, see NIH Guide Notice NOT-OD-12-108.

After Assignment

Contact your Scientific Review Officer 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 <u>Summary Statement</u> in the eRA Commons (paper copies of the Peer Review Outcome Letter and Summary Statement will not be mailed to the PI. Electronic copies may be accessed through 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.

Paper copies of the Peer Review Outcome Letter and Summary Statement will not be mailed to the Fellowship applicant, electronic copies may only be accessed through the eRA Commons.

1.5 Grants Policy Statements

The <u>NIH Grants Policy Statement</u> 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 <u>HHS Grants Policy Statement</u> 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

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

NIH Research Portfolio Online Reporting Tool (RePORT)

Contact Information for an NIH or AHRQ Staff Person

http://ned.nih.gov

NIH locator: (301) 496-4000

Applying Electronically

For additional information on the electronic submission process, including self-help resources, training material and answers to frequently asked questions, see:

http://grants.nih.gov/grants/ElectronicReceipt/index.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. For more details on Commons registration, see Section 2.2.2.

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

eRA Commons Help Desk: http://era.nih.gov/help/

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

E-mail: 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 at the following address: . http://www.grants.gov/documents/19/18243/GrantsgovApplicantUserGuide.pdf

NIH Grants and Funding Help Page

http://grants.nih.gov/support/index.html

This site provides a self-help wizard to guide inquiries to the correct NIH website for additional information on specific topics.

NIH Office of Extramural Research Human Subjects Website

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

This site provides, in one place, HHS 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

https://grants.nih.gov/grants/receipt referral.htm

Division of Receipt and Referral

Center for Scientific Review

Telephone: (301) 435-0715

Fax: (301) 480-1987

Email: csrdrr@mail.nih.gov

Specific Application: Before Review

Telephone or e-mail the Scientific Review Officer 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 e-mail 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 its statutory authorities for awarding grants, contained in Sections 301(a) and 487 of the PHS Act, as amended (42 U.S.C. 241a and 42 U.S.C. 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the ability of the PHS to review an application and to monitor the grantee's performance.

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 U.S.C. 241a and 42 U.S.C. 288), 42 CFR part 66.

F05 Authority: Section 307, 42U.S.C. 2421 and 42 CFR part 63a.

F37 Authority: Section 472, 42 U.S.C. 286b-3 and 42 CFR part 61.

AHRQ Authority: Section 487, Sections 304, 902, and 935 of the PHS Act, 42 U.S.C. 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 operation 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 2006 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, students 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. Commons IDs are required for individuals holding the following Commons Roles; PI, Undergraduate, Graduate Student, Postdoctoral. Responses to certain data in the Personal Profile are now required to meet NIH reporting requirements to Congress. Note in some cases an acceptable response is "Do Not Wish to Provide." 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 programs (e.g., Ruth L. Kirschstein National Research Service Awards and Research Career Development Awards) citizenship data 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 Section 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 (0925-0001). Do not send applications to this address.

2. Process for Application Submission via Grants.gov

Application submission through Grants.gov involves several steps. 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 <u>Grants.gov</u> and all the resources available there.

2.1 Overview

All registrations require that applicants be issued a <u>Dun and Bradstreet Universal Numbering</u>
<u>System (DUNS)</u> number. After obtaining a <u>DUNS</u> number, applicants can begin both System for Award Management (SAM) (formerly CCR) and eRA Commons registrations. The same DUNS number must be used for all registrations and on the grant application itself.

Note that all applicant and grantee organizations must complete and maintain an active entity registration in SAM which requires renewal at least annually. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. Foreign organizations must obtain a NATO Commercial and Government Entity (NCAGE) Code (in lieu of a CAGE Code) in order to register in SAM. Use the SAM.gov "Manage Entity" function to maintain your entity registrations. See the Grants Registrations User Guide at http://www.sam.gov for additional information.

For additional information regarding maintaining an active SAM registration, please see <u>NIH</u> Guide Notice NOT-OD-11-004.

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.

- Register your organization at <u>Grants.gov</u>. (This is a one-time only registration process for all Federal agencies. However, an annual renewal of information provided to the <u>System for</u> <u>Award Management (SAM)</u> is necessary to retain active Grants.gov credentials. 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 <u>Section 2.2</u> for more details.)
- 2. Register your organization. eRA Commons registration is also required for the Fellowship applicant (who is designated as the Program Director/Principal Investigator, or PD/PI) and for the primary Sponsor designated on the grant application. See NOT-OD-14-129 for additional details. (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) of interest using the <u>NIH Guide for Grants and Contracts</u> or <u>Grants.gov's "Search Grants"</u> feature. (See <u>Section 2.4</u> for more details.)
- 4. Download the associated Application Package from Grants.gov. (Adobe Reader required for download. See Section 2.3.1 for more details.)
- 5. Complete the appropriate application forms, including all text and PDF attachments. Upload all attachments into the appropriate application form (See Section 2.6 for more details on the requirements for text (PDF) attachments).
- 6. Review the completed application through your own organizational review process.
- 7. Coordinate with an Authorized Organization Representative (AOR) at the applicant organization to submit the application by the date and time specified in the FOA. (Keep a copy locally at the Applicant Organization/Institution.)
- 8. Receive the Grants.gov tracking number.
- After successfully passing Grants.gov and agency validation, receive the agency tracking number (accession number). Note: Any errors encountered at Grants.gov or eRA Commons must be corrected in order to successfully complete your submission successfully.
- 10. The Fellowship applicant and Signing Official (SO) must complete a verification process in the eRA Commons to ensure the assembled application correctly reflects their submission. (See Section 2.11 for detailed information.)

The following sections explain each step in more detail.

2.2 Registration Process

New/potential applicant organizations must have completed both Grants.gov and eRA Commons registrations in order to submit an application. Grants.gov and eRA Commons are distinct, one-time registrations which may be completed simultaneously. Each registration process is described below.

2.2.1 Grants.gov Registration

Grants.gov requires a **one-time** registration *by the applicant organization* in order to submit applications. Registration is not needed to download an application package or to prepare an application for submission. Fellowship applicants do not have to individually register in Grants.gov unless they also serve as the Authorized Organization 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 eRA Commons registration steps noted below. For those applicant organizations still needing to register with Grants.gov, registration information can be found at the Grants.gov "Applicants" tab. 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 at least six (6) weeks to complete all the steps before actually submitting an application through Grants.gov.

All registrations require that applicants be issued a <u>Dun and Bradstreet Universal Numbering</u>
<u>System (DUNS)</u> number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations and on the grant application itself.

Note that all applicant and grantee organizations must complete and maintain an active entity registration in the System for Award Management (SAM), which requires renewal at least annually. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. Foreign organizations must obtain a NATO Commercial and Government Entity (NCAGE) code (in lieu of a CAGE code) in order to register in SAM. See the SAM.gov "Help" tab for links to the full User Guide, Quick Start Guides, helpful hints, and other information.

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 e-mail 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), all individuals with the role of project lead on multi-project applications, and individuals with the role of Sponsor on individual fellowship applications must also complete a one-time registration in the eRA Commons as a requirement for application submission. Access to the Commons is vital for all steps in the process after application submission. An organization, Fellowship applicant, and individuals in other roles that require an ID must be registered in the Commons in order to have access to electronic submission and retrieval of grant information, such as reviewing grant applications, institute/center assignments, review outcomes, and Summary Statements (access varies by type of role). Applicants must have an active DUNS number in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO), also known as the Authorized Organization Representative (AOR in Grants.gov), and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application. Institutional/organizational officials are responsible for registering Fellowship applicants and other individuals with a role in NIH progress reports in the eRA Commons. Individuals seeking individual fellowship support should work with their AOR/SO to determine their institutional/organizational process for registration.

IMPORTANT: The eRA Commons registration process should be started at least six (6) 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 Form 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 Commons Registered Organizations link at https://public.era.nih.gov/chl/public/search/index.jsp.

To register an Organization in the eRA Commons:

- 1. Complete the online Institution Registration Form at: https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp
- 2. Print and fax the registration page
 - a. The Signing Official (SO) must sign, date and fax the registration to the number listed on the form
- 3. Signing Official must verify email address
 - a. Once the registration is submitted electronically, email verification is sent and the SO must click the link to verify email
 - b. The above steps must be completed before NIH can process the registration
 - c. The SO will receive an "Approval" email from NIH
 - d. The "Approval" email contains a link to information that you must verify as correct before the confirmation process is completed
- 4. Account Administrator (AA) receives user names and temporary passwords
 - a. After the completion of the confirmation, the SO and AA will receive two emails that contain the user names and temporary password for the SO and AA accounts created during the registration process
- 5. Log into Commons
 - a. The SO and AA log into Commons and administer additional accounts as needed
- 6. Affiliate your PD/PIs
 - a. Your Principal Investigators must work with your organization to be registered in eRA Commons if they do not have an existing account. IF they have an account, you must affiliate it with your organization. Verify that you've selected the correct PI account!

For more information, see http://era.nih.gov/commons/faq commons.cfm#II2

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

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 eRA Commons https://public.era.nih.gov/chl/public/search/index.jsp. 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 Directors/Principal Investigators PD/PIs)

The individual Fellowship applicant for whom support is being requested is designated as the PD/PI on the application and must be registered in the Commons. 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. The initial registration must be done by an Authorized Organization Representative (AOR) who has the SO role in Commons, or other authorized accounts administrator at the organization. However, after the initial registration process is complete, it becomes the responsibility of each individual to maintain the information in his/her personal profile. If submitting an application reflecting Multiple PD/PIs, the individual designated as the contact PI must be affiliated with the applicant organization.

To register Fellowship applicants in the Commons, refer to (http://era.nih.gov/commons/userguide.cfm).

Once a Fellowship applicant has received e-mail 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. The Fellowship applicant should 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), e-mail, 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 Commons since each role enables different features within eRA Commons. For example, an SO can Reject a submitted application to prevent it from being sent on to agency staff. A PI has access to review outcome information (scores and summary statement). If you are the SO for your organization as well as a PD/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://grants.nih.gov/grants/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 e-mail address to the administrator of the new sponsoring organization. (The e-mail 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 e-mail 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, select the Frequently Asked Questions tab and search for affiliations.

2.2.2.3 Commons Registration for the Sponsor

A valid eRA Commons Username is required for the primary Sponsor designated on a competing individual Fellowship grant application.

Note that if the sponsor has an existing eRA Commons account with the PI or other scientific roles, 'Sponsor' role should be added to the existing account rather than creating a new account.

See NOT-OD-14-129 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-129.html)

2.3 Software Requirements

2.3.1 Adobe Reader

In order to access, complete and submit applications using Grants.gov's downloadable forms, applicants will need to download and install a compatible version of the Adobe Reader available at the Grants.gov website http://www.grants.gov/web/grants/support/technical-support/software/adobe-reader-compatibility.html.

For minimum system requirements and download instructions, please see the <u>Grants.gov User</u> Guide

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 form 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. Do not use the ampersand (&) character in file names. Use one space, (not two or more) between words or characters. Just like letters, a space counts as one character.

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 free PDF-creation software, Grants.gov has published a list of available tools and software, see Grants.gov's Download Software page at http://www.grants.gov/web/grants/support/technical-support/software/pdf-conversion-software.html.

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.

See additional information at NIH PDF Guidelines http://grants.nih.gov/grants/ElectronicReceipt/pdf guidelines.htm

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 other PHS agencies, any other agency of the United States Government, or any employee of the United States Government. No warranties are stated or implied.

2.4 Funding Opportunities

Grants for health-related research and research training projects or activities make up the largest category of funding provided by the NIH Institutes/Centers (ICs) and other non-NIH agencies. Most applications for support are unsolicited and originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the NIH. All submissions to Grants.gov require a FOA. For a list and brief description of grant activity codes, see Supplemental Instructions 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

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

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 <u>Grants.gov</u>. 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 modifications 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 Grants.gov under Search Grants (http://www.grants.gov/web/grants/search-grants.html). 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 Search Grants, 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 "Posted Date" refers to the date the FOA is posted on <u>Grants.gov</u>. 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 "open date" to submit the application.
- An application can be submitted anytime between the "open date" and the "application due 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 prepopulated. 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.

All applications submitted to the NIH and AHRQ must be submitted in response to an FOA published in the NIH Guide for Grants and Contracts.

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 "Search Grants" (a.k.a. "Search") and "Apply for Grants" (a.k.a. "Apply"). From the "Applicants" section of the Grants.gov home page, select "Apply for Grants" and follow the steps provided. FOAs posted in Grants.gov "Search" 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 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 Required Application Instructions section. This link is only provided in those announcements involving electronic submission through Grants.gov.

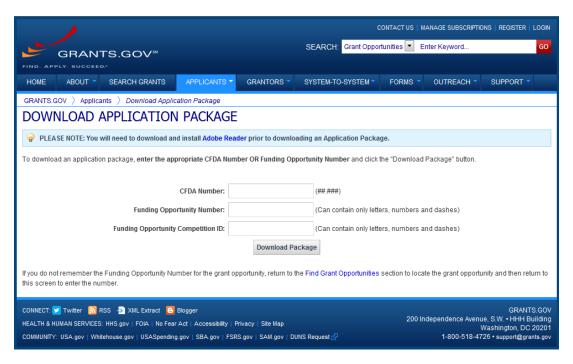
Using "Search" Grants

Grants.gov Search Grants provides general search capabilities. From the "Search Grants" page, you will find various options for: providing search criteria (e.g., keyword, Funding Opportunity Number, status, etc.) and identifying FOAs of interest.

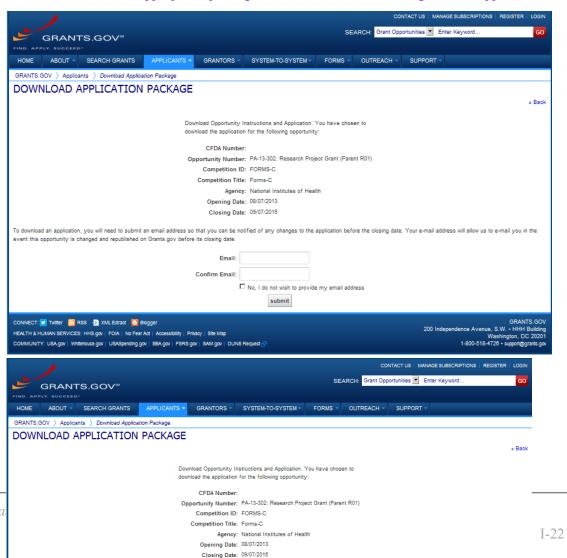
Once you find an opportunity for which you wish to apply, you may initiate the application download process from the Search page by selecting the FOA then selecting the "Application Package" tab and using the download link.

Using "Apply for Grants"

If you know the specific Funding Opportunity Announcement (FOA) number, from the Grants.gov homepage, select "Applicants" then "Apply for Grants" and follow the steps provided. "Step 1" allows you to download an application package by inserting an FOA number. If you do not know the specific FOA Number you may use Search Grants to find it.



Click the corresponding **download** link to access the actual application form pages and instruction material. If more than one application package is listed, use the Competition ID and Competition Title to determine the appropriate package to download. The following screens appear:



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 website 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 forms for 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 AHRQ are strongly encouraged to complete this information. The agency can then use it to provide additional information to prospective applicants.

Note: The forms may or may not show a CFDA number and the CFDA field is not editable. Do not be concerned. The CFDA number is not used 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 Forms for an Application to NIH or AHRQ

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

DOCUMENT	REQUIRED	OPTIONAL	INSTRUCTIONS
SF424 (R&R)	x *		Section 4.2
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 Expanded	x		Section 4.5
PHS Fellowship Supplemental Form	x		Section 5.3
Planned Enrollment Report		x	Section 5.8
PHS 398 Cumulative Inclusion Enrollment Report		x	Section 5.8.2

Table 2.5-1. Forms for an NIH or AHRQ Application

^{*} Fellowship applicants are required to include a cover letter with the application. The cover letter must contain the list of referees (see <u>SF424 (R&R) form, Item 21, Cover Letter Attachment</u> for instructions). 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. Forms from other sources 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-enforced 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 AHRQ 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://grants.nih.gov/grants/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. Do not use the ampersand (&) character in file names. Use one space, (not two or more) between words or characters. Just like letters, a space counts as one character.

Font

Prepare the application using Arial, Helvetica, Palatino Linotype, or Georgia typeface in black font color. After text attachments are converted to PDF, font size in each final PDF document must be at least 11 points (or larger). (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Since some PDF converters may reduce font sizes, it is important to confirm that type density in each final PDF document, including both characters and spaces, is no more than 15 characters+spaces per linear inch and no more than six lines per vertical inch.

Paper Size and Page Margins

Final PDF documents should be formatted to be no larger than standard paper size (8 ½" x 11).

The final PDF document should have 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 announcements must still be followed. Agency validations will include many 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 may not address all page limit requirements for a specific FOA and 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 5 pages per person. See Biographical Sketch instructions in Section 4.5 Senior/Key Person Profile (Expanded) Form.

For the applicant fellow, see Fellowship Application Biographical Sketch Form Page at http://grants.nih.gov/grants/funding/424/applicant-fellowbiosketch.docx. A completed example is found at: http://grants.nih.gov/grants/funding/424/applicant-fellowbiosketchsample.docx. if you are applying for a Senior Fellowship. If you are applying for a predoctoral fellowship use this custom

<u>biographical sketch page</u>. If you are applying for a postdoctoral fellowship, use this <u>custom</u> biographical sketch format page.

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 biosketchsample VerC.docx.

Applicants must observe the page numbers given in the detailed Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless the FOA specifies otherwise. All tables, graphs, figures, diagrams, and charts must be included within the Research Strategy page limit. If PAs or RFAs contain specific page limits, those instructions always supersede these instructions.

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
PHS Fellowship Supplemental Form B. Research Training Plan Introduction - Resubmission applications	1 page with resubmission	See Instructions in Section 2.7
Research Training Plan B.2 Specific Aims B.3 Research Strategy Sections B.4	1 page 6 pages total No limit	Text including all figures, charts, tables, and diagrams.
Human Subjects Sections B.5 through 10	No limit	See Instructions in Section 5.3
Other Research Training Plan Sections Sections B.11 through 14	No limit	See Instructions in Section 5.3
Respective Contributions Section B.15	1 page	See Instructions in Section 5.3
Selection of Sponsor and Institution Section B.16	1 page	See Instructions in Section 5.3
Responsible Conduct of Research Section B.17	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

SECTION	PAGE LIMIT (MAXIMUM PAGE LIMIT LISTED)	CONTENT
PHS Fellowship Supplemental Form D. Sponsor and Co-Sponsor		
Applicable to applications using the Adobe B-1 (not B) package only.	6 pages	See Instructions in Section 5.3
PHS Fellowship Supplemental Form F. Appendix	No page limits. (Grants.gov defaults to a maximum of 10 separate attachments)	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

Applicants are prohibited from using any section of the application that does not have specific page limits (e.g. the Appendix or human subjects section) to circumvent page limitations in any section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080.

2.7 "Resubmission" Applications

The National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ) have updated their policies for application submission. Following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for any due date in the future that is appropriate for the grant mechanism and Funding Opportunity Announcement. The policy does not preclude submission of a new (A0) application following an unsuccessful new (A0) application, without an intervening resubmission (A1) application. The NIH and AHRQ will not assess the similarity of the science in the new (A0) application to any previously reviewed submission when accepting an application for review (see NOT-OD-14-074).

The updated policy applies to major types of applications and activity codes, including, the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, Eligibility criteria and any other restrictions or requirements in the Funding Opportunity Announcement (FOA) prevail. For example, an SBIR/STTR application must meet the eligibility requirements for each application submission. An application that was not accepted previously for being too similar to a resubmission application that had been reviewed previously can be submitted as a new application.

NIH's policy for accepting overlapping applications remains in effect (see <u>NOT-OD-09-100</u>). The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

• a new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping resubmission (A1) application.

- a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- an application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101).

The NIH time limit for accepting resubmission (A1) applications remains in effect (see <u>NOT-OD-12-128</u> and <u>NOT-OD-10-140</u>). The NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows.

NIH has established policies for application resubmissions of certain categories. See <u>Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity</u> Code in Part III, 1.2.

There are four requirements for a Resubmission application:

- The Summary Statement from the previous new application that it follows must be available in the eRA Commons (http://commons.era.nih.gov/commons).
- The PD/PI(s) must make significant changes to the application, compared to the new application that it follows.
- An Introduction must be included that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. The Introduction is separate from the Cover Letter. Use Item 2.1 Introduction of the PHS 398 Research Plan Form to provide this information. The page limit for the Introduction may not exceed one page unless indicated otherwise. Please refer to the relevant section of the application instructions and the FOA.
- New Letters of Reference must be submitted electronically through the eRA Commons at https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new, 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.

Reference Letters for Resubmission Application: Applicants must arrange for the resubmission of three reference letters. See Letters of Reference in Part I, Section 5.4 for additional details.

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 two 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, <u>Section 5.4</u> 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 similar grant applications with essentially the same research focus from the same applicant organization for the same receipt date. 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 and not by disease or disease state. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed or the application(s) may not be reviewed. For additional information, see NOT-OD-09-100.

2.10 Submitting your Application Via Grants.gov

The Authorized Organization Representatives (AORs) registered in Grants.gov are 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 Grants.gov 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. Note that the Check Package for Errors button only checks a subset of Grants.gov application checks and does not guarantee that your application will pass subsequent Grants.gov and agency business rule checks done after submission. Only after the package has been saved with no errors will the Save & Submit button become active. Clicking the Save & Submit button will begin the application submission process. 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 Contact Center or the eRA Commons Help Desk.

For additional information, see http://www.grants.gov/applicants/apply for grants.jsp.

Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) **before** 5 p.m. on the receipt date, local time of the applicant organization. Applicants are encouraged to submit their applications to Grants.gov several days early to ensure enough time to correct any errors before the deadline.

2.11 After you Submit your Application via Grants.gov

Grants.gov's Track My Application feature for Applicants (http://www.grants.gov/web/grants/applicants/track-my-application.html) provides basic status information for a specified Grants.gov Tracking Number. The Authorized Organization Representative (AOR) can also login to Grants.gov with their username and password to obtain a more detailed status of an application by using the Check My Application Status feature.

Once an application has been submitted via Grants.gov, several e-mails are sent to the email address on file with Grants.gov for the AOR (known at NIH/in eRA Commons as the Signing Official [SO]) who submitted the application. Each email notification will reference a Grants.gov tracking number that is assigned to the submission:

- 1. Submission Receipt: An e-mail is sent indicating your application has been received by Grants.gov and is currently being validated.
- 2. Submission Validation Receipt: An e-mail 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 e-mail is sent indicating your application has been retrieved by the Grantor agency.
- 4. Agency Tracking Number Assignment for Application: An e-mail is sent indicating your application has been assigned an Agency Tracking Number. In Grants.gov, a status of Agency Tracking Number Assigned also indicates that NIH has processed the application without identifying any errors and an assembled application image is available in eRA Commons for viewing.

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 E-mail: 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 e-mail address provided for the Fellowship applicant (PD/PI) and for the AOR/SO on the SF424 (R&R) form be current and accurate. Once agency validation is completed, an agency notification (not Grants.gov) will be e-mailed to the Fellowship applicant, AOR/SO, and the Applicant Contact e-mail (if provided) named in the application.

This e-mail notification will inform the Fellowship applicant, AOR/SO, and the Applicant Contact (if named) 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, AOR/SO, and the Applicant Contact will be invited to log on the RA Commons to view the assembled application or review the list of warnings/errors that were encountered during the validation process. SOs for the applicant organization, the PD/PI for the application and any Assistants that have been delegated in eRA Commons to view the PD/PIs status information will have access to the submission results in eRA Commons.

If there were no validation errors, this e-mail notification will also inform the PD/PI, AOR/SO, and the Applicant Contact of an agency accession number (e.g., AN654321), which represents the "agency tracking number." The Grants.gov system will indicate that the agency tracking number has been assigned, and will reflect both numbers.

The eRA system will make every effort to send an e-mail to the Fellowship applicant, AOR/SO, and the Applicant Contact summarizing download and validation results. Since e-mail can be unreliable, applicants are responsible for checking on their application status in the Commons.

Once an application package has been successfully submitted through Grants.gov, any encountered errors have been corrected by the applicant, and an application image has been assembled by the eRA Commons, PD/PIs and AORs/SOs will have two business days (Monday – Friday, excluding Federal holidays) to check the assembled application before it automatically moves forward to NIH staff for further processing and consideration. Once the application has moved forward, no additional changes to the application will be accepted through Grants.gov or eRA Commons. This window is known as the application viewing window.

Within the viewing window, SOs have the authority to reject an application to stop it from completing the submission process. After an application is rejected, a changed/corrected application can be submitted to address warnings or other issues if it is still before the submission deadline. However, changed/corrected applications overwrite previous submissions and if submitted after the submission deadline will be subject to the NIH Late-Policy and may not be accepted.

Remember, warnings do not stop further application processing. If an application submission results in warnings (but not errors), the application will automatically move forward after the application viewing window if no action is taken. Some warnings may need to be addressed later in the process.

It is your responsibility to view the entire assembled application in eRA Commons and notify the <u>eRA Commons Help Desk</u> within this window if the assembled application does not correctly reflect the information submitted to Grants.gov (e.g., submitted information is missing in image, graph/chart appears upside-down). The eRA Commons Help Desk will provide guidance on appropriate corrective actions.

If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the <u>Guidelines for Applicants</u> Experiencing System Issues.

Only the eRA Help Desk can confirm whether a system issue has taken place and provide instructions on how to resolve the issue. Applications affected by confirmed system issues will not be considered late as long as the applicant works diligently with the eRA Help Desk on a resolution. If the application needs to be Rejected and resubmitted, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications.

PD/PIs should work with their AOR/SO to determine when the "Reject" feature is appropriate.

To view the assembled application the AOR/SO should:

- 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 hit list 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 hit list.

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 hit list 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 application due date, applicants may make corrections and resubmit an application through Grants.gov. If applicants make corrections and resubmit the application after the due date, the application will be considered late. In this case, applicants *must* include a cover letter explaining the reasons for the delay and acceptance will be considered on a case-by-case basis. Also see Section 2.14 for additional information on submission dates.

If errors or warnings result from the validation process, the Fellowship applicant, AOR/SO and Applicant Contact will be issued an e-mail 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 e-mail to the Fellowship applicant, AOR/SO and Applicant Contact indicating whether errors or warnings were detected. However, since e-mail can be unreliable, applicants are responsible for periodically checking on their application status in the eRA Commons, so that any errors or warnings can be resolved in the timeliest manner possible, before the deadline. SOs for the applicant organization, the PD/PI for the application and any Assistants that have been delegated in eRA Commons to view the PD/PIs status information will have access to the submission results in eRA Commons.

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, at least for the time being, but worthy

of bringing to the applicant's attention. It is at the applicant's discretion whether a warning condition requires any action, but some warnings may need to be addressed later in the process.

Failure to comply with stated NIH policies can also result in a submitted application that will not be considered for 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.

Submitting a Changed/Corrected application will overwrite the previous submission and the previous application cannot be reinstated.

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

- After the application has been downloaded from Grants.gov and validated by the system, login to the eRA Commons (https://commons.era.nih.gov/commons/) using your username and password.
- 2. Click the **Status** tab on the Commons menu bar.
- 3. Click Recent/Pending eSubmissions.
- 4. Search for your application by date received, Grants.gov tracking number, or accession number, if you are the SO. If you are the Fellowship applicant (PI), clicking Recent/Pending eSubmissions will automatically display a hit list of your applications.
- 5. A hit list of applications is displayed. If the application was validated with warnings only, or without encountering any problems whatsoever, then it is identified in the hit list 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 hit list, 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 hit list (Application Status will read "eSubmission Error" if errors were received), use the Show Prior Errors link to view the list of errors/warnings.
- 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 also disregard the warnings and proceed to view the application, as described earlier.

To correct errors and resubmit the application:

Make whatever corrections are necessary, wherever appropriate, to your local copy of the
application. Most often this means that you have to edit the data within the application forms
to correct whatever problem or inconsistency that was noted. Be as careful as possible
when correcting your application; NIH's post-submission materials policy does not allow for
applicants to correct oversights in their application after the due date.

- 2. Check the "Changed/Corrected Application" box in the Type of Submission field of the SF424 (R&R) form.
 - If you are submitting this Changed/Corrected application after the due date, be sure to document the reason for the late submission in the form of a cover letter. NIH makes no guarantees that applications submitted after the due date will be accepted. See the NIH late policy for more information.

When you check the Changed/Corrected Application box, Previous Grants.gov Tracking ID field becomes a required field. Enter the Grants.gov Tracking ID (GRANT87654321) of the previous submission that you are correcting.

- When you have made all of your corrections, save the Changed/Corrected application to your computer
- 3. The AOR will have to submit the Changed/Corrected application package to Grants.gov. A new Grants.gov tracking number will be assigned and the applicant will have to follow the Changed/Corrected application through Grants.gov to the eRA Commons to view the application image or the list of errors/warnings received during the validation process. It is the applicant's responsibility to track the application through to the eRA Commons. If you cannot view your application image in the Commons, NIH can't review your application! Successful submission may take several rounds of Changed/Corrected applications, since correcting one error may reveal or create an additional error.

The same e-mail notifications will be issued once the agency has downloaded and validated the resubmitted application and the Fellowship applicant, AOR/SO, and Applicant Contact 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 Post-Submission Application Materials

Grant application materials will only be accepted after submission of the application but before the initial peer review if they result from unforeseen administrative issues. Exceptions to this policy are indicated below. See NOT-OD-10-091 and NOT-OD-13-030 for additional information.

The materials should be sent by the Signing official to the Scientific Review Officer (SRO) as a PDF attachment to an e-mail. E-mail communication is preferred. If e-mail is not feasible, please send a hard copy, addressed to the SRO.

The original application is kept intact; any application material sent post-submission is sent separately by the SRO to the 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.

Acceptable post-submission materials include:

- Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition)
- Biographical sketches (e.g., change in senior/key personnel due to the loss of an investigator)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution (e.g., PD/PI moved to another university)
- News of an article accepted for publication
- News of a professional promotion or positive tenure decision for any Program
 Directors/Principal Investigators and Senior/Key Personnel also will be accepted as postsubmission application material. The news must be received by the Scientific Review
 Officer one month (30 calendar days) prior to the peer review meeting, and demonstrate
 concurrence from the Authorized Organization Representative (AOR) of the applicant
 organization.
- Information on Sponsor's Research Funding: Because the Sponsor(s)' funding is a major factor in the review of a Fellowship application, this information will be allowed as post-submission material to update the Sponsor(s)' funding information in the originally submitted application. Information on the Sponsor(s)' funding information must not exceed 1 page, and is limited to the project title, funding source (e,g. NIH grant number), a brief description of specific aims, and relevance to the fellowship application under review. The additional material is due no later than 30 days prior to the meeting of the review committee (see NOT-OD-12-111).
- If an application proposed to use a human embryonic cell line(s) that is approved by the NIH Stem Cell Registry at least 30 days prior to the peer review meeting, the SRO can include this update to the reviewers as part of the post-submission materials (see NOT-OD-12-111).
- Videos, within defined limits, (see <u>NOT-OD-12-141</u>). Devices and other non-traditional
 materials will not be accepted after submission, unless the application is submitted for a
 Funding Opportunity Announcement that specifies other types of allowable post-submission
 materials.

Unacceptable post-submission materials [for all applications but those under Exceptions below] include:

- Updated Specific Aims or Research Strategy pages
- Late-breaking research findings
- Supplemental pages information not contained in the existing application
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the loss of an investigator

Exceptions to this policy include:

 Applications submitted in response to Requests for Applications (RFAs) that have only one due date. Post-submission materials for these applications will be accepted as outlined in NOT-OD-10-070

- Applications submitted in response to Requests for Applications (RFAs) that have multiple due dates, the exception to this policy applies to applications submitted for the last due date of an RFA (see NOT-OD-13-030)
- Certain NIH Funding Opportunity Announcements (FOAs) may allow certain other types of
 post-submission materials to facilitate the goals of the program. Such stipulations must be
 explained in the FOA in the NIH Guide for Grants and Contracts

Page limits for post-submission materials under this policy:

- All post-submission materials must conform to NIH policy on font size, margins, and paper size as referenced in Part I 2.6 of the applicable application instructions
- NIH additional form pages such as budget, biographical sketches, and other required forms must follow NIH standards for required NIH form pages.
- If post-submission material is not required on a form page, each explanation or letter is limited to one page (see Acceptable post-submission materials above)

The additional materials must be submitted to the NIH SRO with the concurrence of the applicant organization's designated AOR/SO. Although the content of post-submission materials may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or organizational officials, the AOR must send the materials directly to the SRO, or must send his/her concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR 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 <u>NIH Chief Grants Management Officer</u> 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 <u>Just-In-Time</u> process (see <u>Part III.1.7</u>).

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 Section 2.15, 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 at this website: http://grants.nih.gov/grants/funding/submissionschedule.htm

Applications submitted for the Standard Submission Dates listed 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 specified Application Due Date(s). 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 Due Dates. When an application submission due date falls on a weekend or <u>Federal holiday</u>, the application deadline is automatically extended to the next business day. The application will be on time if it is submitted on or before the following business day.

Late Applications. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a cover letter attachment explaining the reasons for the delay must be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. See NIH NOT-OD-11-035 - NIH Policy on Late Submission of Grant Applications. See NIH Guide Notice dated January 13, 2011 - NIH Policy on Late Submission of Grant Applications.

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, attach a Cover Letter to the SF424 (R&R) form using the Cover Letter Attachment field to provide specific information on the timing and nature of the cause of the delay. No other documentation is expected. Late applications are evaluated on an individual basis considering the reasons provided. Contacting the <u>Division of Receipt and Referral, Center for Scientific Review (CSR)</u>, NIH, or any other NIH official in advance will not influence the acceptance of a late application.

Related Guide Notices include:

• NOT-OD-11-035 NIH Policy on Late Submission of Grant Applications

2.15 Submission, Review and Award Cycles

The NIH submission, review, and award schedule for Individual Fellowships is provided at this website: http://grants.nih.gov/grants/funding/submissionschedule.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.

<u>Assignment to Review Group</u>. 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 Cover Letter Attachment.

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 the Funding Opportunity Announcement.

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 Scientific Review Officer (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, email csrdrr@mail.nih.gov. If there is a change in assignment, you will receive a notification and the change will be reflected in the eRA Commons.

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

2.16 Resources for Finding Help

2.16.1 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. If you are on deadline for submitting an application and are experiencing technical difficulties with the submission, contact the Grants.gov and eRA Commons Help Desk immediately.

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 Self-Service Web Portal: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Grants.gov Help Desk: support@grants.gov

Grants.gov Contact Center Phone Number: 800-518-4726 (Toll Free), 606-545-5035 (Local or International)

The Contact Center is available 24 hours a day, 7 days a week (except Federal holidays).

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 Fellowship PD/PIs; with using ASSIST, or with the application validation process in the Commons after submission through Grants.gov, check first the resources available at the Applying Electronically website: (http://grants.nih.gov/grants/ElectronicReceipt/).

eRA Commons customer support is also provided by the eRA Commons Help Desk:

eRA Website: http://era.nih.gov

eRA Commons Website: https://commons.era.nih.gov/commons/index.jsp

eRA Commons On-line Resources and Web Ticketing: http://grants.nih.gov/support

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

The eRA Commons Help Desk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time (except Federal holidays).

NOTE: To help expedite your Help Desk request, we recommend that you have the following information readily available (NOTE: Additional details may be required depending upon the type of issue/request):

- Full Name of Affected User
- Full Name of Institution/Organization
- Grants.gov Tracking Number
- Submission Date
- Funding Opportunity Announcement (FOA)
- Principal Investigator's (PI) Username
- Signing Official's (SO) Username

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 E-mail: GrantsInfo@nih.gov

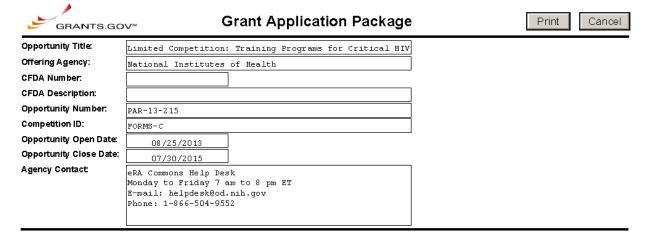
3. Using the Grant Application Package

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



<u>CFDA Number Field:</u> 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.

<u>Opportunity Open Date & Close Date Fields:</u> 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, applicants should refer to the PHS submission, review, and award schedule 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

Click the form name to navigate to the form in the application package and complete all of the Mandatory forms. Complete the form titled SF 424 (R&R) first. Data entered in this form populates other mandatory and optional forms where applicable.

Select Form	Mandatory	
Mandatory		
S	F424 (R & R)	
	HS Fellowship Supplemental Form	
	esearch and Related Senior/Key Person Profile (Expanded)	
	esearch And Related Other Project Information	
	roject/Performance Site Location(s)	

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.

to the form, click on the form name. To remove an optional form from the application package, uncheck the box next to the form name.		
Optional		
Planned Enrollment Report		
PHS 398 Cumulative Inclusion Enrollment Report		

Click the check box next to the form name to add the form to the application package. To navigate

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 fields required by Grants.gov 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 Grants.gov registration process (if not connected to the internet you will be instructed to do so).

4. Completing the SF 424 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 on SF 424 (R&R) forms used federal-wide are denoted by the HHS 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.

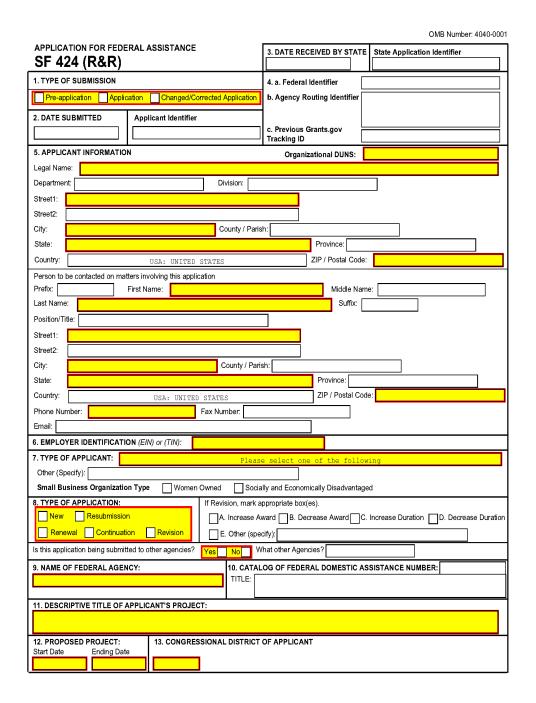
As you navigate through the Grants.gov forms, required fields are outlined in red. Data entered into a specific field is not accepted until you have navigated to the next field. If you enter invalid or incomplete information in a field, you will receive an error message.



Note the outlined fields required for submissions, and the **Check Package for Errors** button, only refer to Grants.gov requirements and errors. They do not reflect all NIH requirements or business processes. NIH validations will be performed by the eRA Commons system after the application has been submitted.

For those forms 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 SF 424 (R&R) Form



1. Type of Submission

Check one of the Type of Submission boxes. If this submission is to change or correct a previously submitted "New", "Resubmission", "Renewal", or "Revision" application, click the

Changed/Corrected Application box and enter the Grants.gov tracking number in the Previous Grants.gov Tracking ID field.

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 Funding Opportunity Announcement, the Pre-application option is not used by NIH and other PHS agencies.

Changed/Corrected Application: This box must be used if you need to submit the same application again to correct system validation errors, application assembly problems, or to incorporate other changes. When submitting a Changed/Corrected Application:

- If submitting after the submission date, include an explanation in the Cover Letter attachment.
- Submitting a Changed/Corrected application replaces the previous submission and removes the previous submission from consideration. Once an application has moved forward to agency staff following the two-day application viewing window, subsequent Changed/Corrected applications will not be accepted unless the application is withdrawn. 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-10-115 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html) for the NIH Policy on Post-Submission Application Materials.
- When you check the Changed/Correct Application box the Previous Grants.gov Tracking ID becomes a required field.
- Do not use the Changed/Corrected Application box to denote a submission of a resubmission or amended application. That will be indicated in the 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 AHRO, leave these fields blank.

4.a. Federal Identifier

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., use CA987654 from 1R01CA987654-01A1). The Federal Identifier is required for Resubmission, Renewal, and Revision applications.

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 (altered or corrected) or amended application. See also the <u>NIH Policy on Resubmission Applications</u>. Institutions submitting revision or renewal applications that are also resubmissions (A1 if allowed, see NIH Guide Notice <u>NOT-OD-09-003</u>,) are instructed to select "Resubmission." For additional information, see NIH Guide Notice <u>NOT-OD-10-052</u>).
- 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 Competing Supplement but proposes a change in 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. In general, changes to the "terms and conditions of the existing award" 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. 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.

4.b. Agency Routing Identifier

Enter the agency-assigned routing identifier per the agency-specific instructions. This is an optional field. Unless specifically noted in a program announcement, the Agency Routing Identifier is not used by NIH or other PHS agencies.

4.c. Previous Grants.gov Tracking ID

Enter the previous Grants.gov tracking number, if applicable.

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	Enter the DUNS or DUNS+4 number of the applicant organization. This field is required. For submission to NIH and AHRQ, this DUNS must match the number entered in the eRA Commons Institutional Profile for the applicant organization. The applicant AOR is encouraged to confirm that a DUNS has been entered in the eRA Commons Institutional Profile (IPF) prior to submitting an application. If your organization does not already have a DUNS number, you will need to go to the Dun & Bradstreet website at http://fedgov.dnb.com/webform to obtain the number. The same DUNS should be used in the eRA Commons IPF, Grants.gov, SAM.gov registrations, and in the DUNS field in the application.	
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 the "Street2" field. This field is optional.	
City	Enter the City for address of the applicant. This field is required.	
County/Parish	Enter the county or parish for address of the applicant.	
State	Enter the State where the applicant is located. This field is required if the applicant is located in the United States.	

Field Name	Instructions
Province	Enter the province. If "Country" is not Canada, please leave blank.
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.	

Field Name	Instructions	
Position/Title	Enter the Position/Title for the person to contact on matters related to this application.	
Street1	Enter first line of the street address for the person to contact on matters related to this application in the "Street1" field. This field is required.	
Street2	Enter the second line of the street address for the person to contact on matters related to this application in the "Street2" field. This field is optional.	
City	Enter the City for address of the person to contact on matters related to this application. This field is required.	
County/Parish	Enter the county/parish for address of the person to contact on matters related to this application.	
State	Enter the State where the person to contact on matters related to this application is located. This field is required if the applicant is located in the United States.	
Province	Enter the province for the person to contact on matters related to this application. If "Country" is not Canada, please leave blank.	
Country	Select the country for the person to contact on matters related to this application address. This field is required.	
ZIP Code	Enter the nine-digit postal code (e.g., ZIP code) of the person to contact on matters related to this application. This field is required if the performance site location is in the United States.	

6. Employer Identification

Enter either TIN or EIN as assigned by the Internal Revenue Service. If your organization is not in the U.S., enter 44-444444. 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); this includes non-U.S. organizations.

7. Type of Applicant



This information is for the Applicant Organization, not a specific individual AOR or Fellowship $\ensuremath{\text{PD/PI}}$

Field Name	Instructions
Type of Applicant	Select the appropriate applicant type code. If Small Business is selected as Type of Applicant, then note if the organization is Woman-owned and/or Socially and Economically Disadvantaged. This field is required. For eligible Agencies of the Federal Government, select X: Other (specify), and then indicate the name of the appropriate Federal agency in the space below.
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 U.S. 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.
	• 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
	the Federal Government's financial obligations or contingent liability from an existing obligation, or
	any other change in the terms and conditions of the existing award.
	Note: Revisions are generally not applicable for fellowship applications.
	Existing definitions for NIH and other PHS agencies Type of Application are somewhat different:
	 New is the same. Check this option when submitting an application for the first time or in accordance with other submission policies. See also the policy Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code Resubmission. Check this option when submitting a revised (altered or corrected) or amended application. See
	also the <u>NIH Policy on Resubmission Applications</u> . Institutions submitting revision or renewal applications that are also resubmissions are instructed to select
	"Resubmission." For additional information, see NIH Guide Notice NOT-OD-10-052, http://grants.nih.gov/grants/guide/notice-files/not-od-10-052.html).
	<u> </u>

Field Name	Instructions
	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.
	This field also affects how you complete the Federal Identifier. If "Type of Application" is "New", you can leave the Federal Identifier field blank unless otherwise specified in the funding opportunity announcement.
	If "Type of Application" is "Renewal," "Revision," or "Resubmission," enter the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1).
If Revision, mark appropriate box(es)	Generally not applicable to fellowships. Leave blank.
Other	If "Other" is selected for Revision, add text to explain.

Field Name	Instructions
Is this application being submitted to other agencies?	Check applicable box. This field is required. 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, 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 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html .
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 field is pre-populated from the opportunity package.

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

This is the Catalog of Federal Domestic Assistance number of the program under which assistance is requested. This field is pre-populated from the opportunity package.



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 200 characters, including the spaces between words and punctuation.

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 00-000.

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.

SF 424 (R&R) APPLICATION FOR FEDERAL ASSIST	TANCE Page 2	
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFO		
Prefix: First Name:	Middle Name:	
Last Name:	Suffix:	
Position/Title:		
Organization Name:		
Department: Division:		
Street1:		
Street2:		
City: County / Paris		
State:	Province:	
Country: USA: UNITED STATES	ZIP / Postal Code:	
Phone Number: Fax Number:		
Email:		
	IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 372 PROCESS?	
a. Total Federal Funds Requested	YES THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372	
b. Total Non-Federal Funds	PROCESS FOR REVIEW ON:	
c. Total Federal & Non-Federal Funds	DATE:	
d. Estimated Program Income	Tricord milionor developed E.e. 12072, ere	
•	PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW	
The list of certifications and assurances, or an internet site where you may obtain this list. 18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Do		
	Add Attachment Delete Attachment View Attachment	
19. Authorized Representative		
Prefix: First Name:	Middle Name:	
Last Name:	Suffix:	
Position/Title:		
Organization:		
Department: Division:		
Street1:		
Street2:		
City: County / Parish:		
State:	Province:	
Country: USA: UNITED STATES	ZIP / Postal Code:	
Phone Number: Fax Number:		
Email:		
Signature of Authorized Representative	Date Signed	
Completed on submission to Grants.gov	Completed on submission to Grants.gov	
20. Pre-application	Add Attachment Delete Attachment View Attachment	
21. Cover Letter Attachment	Add Attachment Delete Attachment View Attachment	

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



The PD/PI is the individual applying for the Fellowship. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the PD/PI profile information contained in the eRA Commons.

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 for the name 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 (family) name of the PD/PI. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) 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. This field is required.
Department	Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Division	Enter the name of primary organizational division, office, or major subdivision 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.
State	Enter the State where the PD/PI is located. This field is required if the PD/PI is located in the United States.

Field Name	Instructions
Province	Enter the province for PD/PI. If "Country" is not Canada, please leave blank.
Country	Select the country for the PD/PI address.
ZIP/Postal Code	Enter the postal code (e.g., ZIP code) of the PD/PI. This field is required if the PD/PI is located in the United States. A nine-digit ZIP Code is required.
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.
E-mail	Enter the e-mail address for the PD/PI. This field is required.

15. Estimated Project Funding

Field Name	Instructions
a. Total Federal Funds Requested	Enter total Federal funds requested for the entire project period. This field is required. Please ensure that the total funds requested reflect the requirements of the applicable fellowship program. 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. If new stipend or other payment levels for Kirschstein-NRSA fellowships are announced after the time of application, these amounts will be automatically adjusted at the time of award.
	Extraordinary Costs. Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring institution or accommodations for fellows who are disabled, as defined by the Americans with Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution in the application or as part of a special written request.
b. Total Non-Federal Funds	Enter total non-Federal funds proposed for the entire project period. This field is required. For NIH and other PHS agencies, enter "0" in this field unless cost sharing is a requirement for the specific announcement.

Field Name	Instructions
c. Total Federal & Non-Federal Funds	Enter total estimated funds for the entire project period, including both Federal and non-Federal funds. This is required information. For NIH and AHRQ applicants, this field will be the same as item 15a unless the specific announcement indicates that cost sharing is a requirement.
d. Estimated Program Income	Identify any Program Income estimated for this project period, if applicable. This field is required. Not applicable to fellowships. Enter \$0.00.

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. One selection is required.

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 <u>Supplemental Instructions Part III</u>, <u>Policies</u>, <u>Assurances</u>, <u>Definitions</u>, and <u>Other Information</u>.

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 (Disclosure of Lobbying Activities) or Other Explanatory Documentation

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



If unable to certify compliance in with the Certification 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 Organization 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 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.

Field Name	Instructions
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.
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. If "Country" is not Canada, please leave blank.
Country	Select the country for the Authorized Representative address.
ZIP/Postal Code	Enter Postal Code (e.g., ZIP code) of the Authorized Representative. This field is required if the Authorized Representative is located in the United States. A nine-digit Zip code is required.
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.
E-mail	Enter the e-mail 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.

Field Name	Instructions
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 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 Funding Opportunity Announcement, NIH and other PHS agencies do not use Pre-applications and this attachment field should not be used for any other purpose.

Not applicable for NIH and AHRQ Fellowships. Leave blank.

21. Cover Letter Attachment

Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the announcement and/or the agency specific instructions.

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 list of referees (including name, department affiliation, and institution). The letter 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(s) (e.g NIH IC). 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 <u>Section 2.14</u>) 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; 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.



List of Referees: All fellowship applicants must include a list of Referees in the Cover Letter Attachment. The list must include the names, degrees, and affiliations of the individuals 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/co-sponsor of this application cannot be counted as a reference. The sponsor's/co-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. Be sure to alert the referees well in advance of the application submission date.
- Failure to provide at least three references may delay processing of your application or may result in the application being returned to you without review.

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.

4.3 Project/Performance Site Locations Form

Pı	roject/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 Organization Name: DUNS Number: * Street1: Street2: * City: * State: Province: * Country: USA: UNITED STATES	l 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. County:
* ZIP / Postal Code:	* Project/ Performance Site Congressional District:
Additional Location(s)	Add Attachment Delete Attachment View Attachment

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.

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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 the FOA, do **not** check the "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" box.

If a Training Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR part 46 and other NIH human subject related policies described in Supplemental Instructions 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 all Training Sites hold an OLAW-approved Animal Welfare Assurance. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance, the applicant must obtain an Interinstitutional 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 form.

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. The DUNS Number is a required field for the Primary Performance Site.
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.

Field Name	Instructions
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.
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 for the primary performance site location. If "Country" is not Canada, please leave blank.
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	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 all districts in a state are affected, enter "all" for the district number. Example MD-all for all congressional districts in Maryland.
	If nationwide (all districts in all states), enter US-all.
	If the program/project is outside the U.S., enter 00-000.
	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.
	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.

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. This field is optional.
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
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. If "Country" is not Canada, please leave blank.
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 Project Performance Site is located in the United States.

Field Name	Instructions
Project/Performance Site Congressional District	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 all districts in a state are affected, enter "all" for the district number. Example MD-all for all congressional districts in Maryland.
	If nationwide (all districts in all states), enter US-all.
	If the program/project is outside the U.S., enter 00-000.
	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.
	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.

For additional performance site locations, click **Next Site** to display the fields for Project/Performance Site Locations 2 through 300.

If you need to add more than 300 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 Form

RESEARCH & RELATED Other Project Information	OMB Number: 4040-0001 Expiration Date: 6/30/2016
1. Are Human Subjects Involved? 1.a. If YES to Human Subjects Is the Project Exempt from Federal regulations? Yes No	
If yes, check appropriate exemption number.	
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:	
Is proprietary/privileged information included in the application? Yes No	
4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment?	
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 as environmental impact statement (EIS) been performed?	ssessment (EA) or
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?	No
6.a. If yes, identify countries:	<u> </u>
6.b. Optional Explanation:	
7. Project Summary/Abstract	View Attachment
8. Project Narrative Add Attachment Delete Attachment View A	Attachment
9. Bibliography & References Cited Add Attachment Delete Attachment	ment View Attachment
10. Facilities & Other Resources Add Attachment Delete Attachment	nt View Attachment
11. Equipment Delete Attachment View Attachm	nent
12. Other Attachments Add Attachments Delete Attachments View Attachments	

NOTE: Form 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.



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. If yes, check the appropriate exemption number.

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.html.



OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (http://answers.hhs.gov/ohrp/categories/1564). 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 <u>Just-In-Time</u> requirement.

Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA), Multiple Project Assurance (MPA), Single Project Assurance (SPA) Number or Cooperative Project Assurance Number that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has an 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 the Certification signature section of the SF424 (R&R) form, is declaring that it will comply with 45 CFR 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.

- 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. This field is required.



Note that the generation of custom antibodies constitutes an activity involving vertebrate animals. If animal involvement is anticipated within the period of award but plans are indefinite, check "Yes" and add the PHS Fellowship Supplemental Form, Vertebrate Animals, attachment to provide an explanation and to indicate when it is anticipated that animals will be used. If an award is made prior to the involvement of animals, the grantee must provide all of the information required by adding a PHS Fellowship Supplemental Form, Vertebrate Animals, attachment in the Research Plan and verifying an IACUC approval to the awarding component. 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. Click Yes if an IACUC review is pending. Click **No**, if no review is pending.



Check "Yes" even if the IACUC review and approval process has not yet begun.

IACUC Approval Date

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



IACUC approval must have been granted within three years to be valid. Note that an IACUC Approval Date is not required at the time of submission. NIH does not require verification of review and approval of the proposed research by the IACUC before peer review of the application. However, this information is required under <u>Just-In-Time Policy</u>.

Animal Welfare Assurance Number

Enter the Federally approved assurance number, if available.



Enter "None" if the applicant organization does not have an OLAW-approved Animal Welfare Assurance. To determine if the applicant organization holds an Animal Welfare Assurance, see the lists of Domestic and Foreign Assured institutions. Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution. When an applicant organization does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested 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.



If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. Although the grantee institution and the PD/PI will be consulted about any such disclosure, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR Part 5). If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA.

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 wasted, 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?

Check yes or no. This field is required.

4.d. If yes, please explain

Enter additional details about the EA or EIS.

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 involves 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 Supplemental Instructions 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 you have checked "Yes" to 6, applicants to the NIH and AHRQ must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), 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 **Project Summary** 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 plan 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 <u>font and margin specifications</u>. 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 <u>Section 2.6</u> 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 AHRQ applications, 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 Plan form is required for NIH and AHRQ applications. Refer to Section 5.3, PHS Fellowship Supplemental Form, Section B, items 2 (Specific Aims) and 3 (Research Strategy) Section 5.5, Research Plan, 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 form (see Section 5.3 for details on completing that form). 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 PubMed ID (PMID) 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 attachment. See Section 5.

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



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. Additional Educational Information

Some FOAs require additional educational information and the applicants must refer to the relevant FOA and follow the instructions to provide the required information. Applications lacking the required attachment will be considered incomplete and will not proceed to review.

3. 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) Form

OMB Number: 4040-0001

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

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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 form provides the ability to collect structured data for up to 100 senior/key persons. Data must be entered for the first 100 individuals (PD/PI + 99 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) form. See instructions in Section 4.2 SF 424 (R&R) form 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	Pre-populated from the SF 424 (R&R). It is the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Pre-populated from the SF 424 (R&R). It is the first (given) name of the PD/PI. This field is required.
Middle Name	Pre-populated from the SF 424 (R&R). It is the middle name of the PD/PI.
Last Name	Pre-populated from the SF 424 (R&R). It is the last (family) name of the PD/PI. This field is required.
Suffix	Pre-populated from the SF 424 (R&R). It is the suffix (e.g., Jr, Sr, PhD) for the name of the PD/PI.
Position/Title	Pre-populated from the SF 424 (R&R). It is the title of the PD/PI.
Department	Pre-populated from the SF 424 (R&R). It is the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Organization Name	Pre-populated from the SF 424 (R&R). It is the name of the organization of the PD/PI.
Division	Pre-populated from the SF 424 (R&R). It is the name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	Pre-populated from the SF 424 (R&R). It is the first line of the street address for the PD/PI . This field is required.
Street2	Pre-populated from the SF 424 (R&R). It is the second line of the street address for the PD/PI. This field is optional.

Field Name	Instructions
City	Pre-populated from the SF 424 (R&R). It is the city for the address of the PD/PI.
County/Parish	Pre-populated from the SF 424 (R&R). It is the county or parish for the address of the PD/PI.
State	Pre-populated from the SF 424 (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	Pre-populated from the SF 424 (R&R). It is the Province where the PD/PI is located. If "Country" is not Canada, please leave blank.
Country	Pre-populated from the SF 424 (R&R). It is the country for the PD/PI address.
ZIP Code	Pre-populated from the SF 424 (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	Pre-populated from the SF 424 (R&R). It is the daytime phone number for the PD/PI. This field is required.
Fax Number	Pre-populated from the SF 424 (R&R). It is the fax number for the PD/PI.
E-mail	Pre-populated from the SF 424 (R&R). It is the e-mail address for the PD/PI. This field is required for PD/PI.

Field Name	Instructions
Credential, e.g., agency login	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. 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 and must have the PI role in eRA Commons. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.
Project Role	Select one. Use "Other" if a category is not listed in the pick list. Select Program Director/Principal Investigator for the Fellowship applicant.
Other Project Role Category	Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist.
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., R.N.). This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information.

Field Name	Instructions
Attach Biographical Sketch	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 here. This is required information. For Fellowship applications, the PD/PI is the Fellowship applicant. Biographical sketches should follow the format described below.
	PD/PI (Applicant) Biographical Sketch (MS Word)
	The Applicant Biographical Sketch Format Page is available only in MS Word format.
	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.
	If you are applying for a predoctoral fellowship, <u>use this custom</u> biographical sketch format page.
	If you are applying for a postdoctoral fellowship, <u>use this custom</u> biographical sketch page.
	If you are applying for a Senior Fellowship, use the traditional Biographical Sketch Format Page.
	The Applicant Biographical Sketch for all fellowship levels may not exceed five pages per person. This 5-page limit includes the table at the top of the first page. Sample biosketches for predoctoral and postdoctoral fellows are available for your use.
	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.
	Education/Training
	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

Field Name	Instructions
	received or expected, in addition to other information requested.
	A. Personal Statement
	Briefly describe why you are well-suited to receive the award for which you are applying. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.
	B. Positions and Honors
	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 start/end dates, field, name of institution/company, and the name of your supervisor/employer. If you are not currently located at the applicant organization, include your projected position at the applicant organization as well.
	C. Contributions to Science
	Considering your level of experience, briefly describe up to five of your most significant contributions to science. This may include research papers, abstracts, book chapters, reviews. etc. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can list audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models;

Field Name	Instructions
	protocols; and software or netware that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Please also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine. Manuscripts listed as "pending publication" or "in preparation" should be included and identified. Indicate if you previously used another name that is reflected in any of the citations.
	D. Scholastic Performance
	Predoctoral applicants: Using the chart provided, list by institution and year all undergraduate and graduate courses with grades.
	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.
	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 levels required for a passing grade.
Attach Current & Pending Support	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 Supplemental Instructions Part III, Policies, Assurances, Definitions and Other Information.

Profile – Senior/Key Person



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" or "Other Professional" in the drop down menu, then indicate in the blank "Sponsor" or "Co-Sponsor" or "Dissertation Advisor, Statistician, and other Consultants" 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 100 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 100 senior/key persons, the "Additional Senior/Key Person Profiles" fields will become available once data for the first 100 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.
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.

Field Name	Instructions
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 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. If "Country" is not Canada, please leave blank.
Country	Select the country for the Senior/Key Person address. This field is required.
ZIP Code	Enter the Postal Code (e.g., ZIP code) of Senior/Key Person. This field is required if the Senior/Key Person is located in the United States. A nine-digit Zip code is required.
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.
E-mail	Enter the e-mail address for the Senior/Key Person. This field is required for the Senior/Key Person.

Field Name	Instructions
Credential, e.g., agency login	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. For NIH and AHRQ, registration in the eRA Commons for all Fellowship applicants (PD/PIs) is required, but optional for the sponsor and co-sponsor(s).
Project Role	Select one. Use "Other" if a category is not listed in the pick list. 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."
Other Project Role Category	Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist. For Fellowships, enter Sponsor, Co-sponsor, Dissertation Advisor(s), Statisticians, and other consultants, as applicable.
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., R.N.). This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information. Applicants should ensure that their degree information is current in their Commons Profile.

Field Name	Instructions
Attach Biographical Sketch	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. Use for Sponsor, Co-Sponsor and other senior/key personnel following the format described below.
Attach Current & Pending Support	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 Supplemental Instructions Part III, Policies, Assurances, Definitions and Other Information.

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, refer to Other Support in Supplemental Instructions 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 <u>Biographical Sketch Format Page</u> to prepare this section for **all** Fellowship applications. Include biographical sketches of all **senior/key personnel**. The Biographical Sketch may not exceed five pages per person. This 5-page limit includes the table at the top of the first page. See the sample of a <u>completed Biographical Sketch</u>.

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 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 you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.
- 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. Contributions to Science. Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central findng(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can list audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.
- D. **Research Support**. List both selected ongoing and completed research projects for the past three years (Federal or non-Federal support). *Begin with the projects that are most relevant to the research proposed in the application*. Briefly indicate the overall goals of the projects and responsibilities of the 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.

5. Completing PHS Fellowship Specific Forms

5.1 Overview

In conjunction with the SF424 (R&R) forms, NIH and AHRQ Fellowship applicants should also complete and submit additional forms titled "PHS Fellowship Supplemental Form." Note the PHS Fellowship forms 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) forms. A complete application to NIH and AHRQ will include SF424 (R&R) and PHS Fellowship forms.

5.2 (Reserved)

5.3 PHS Fellowship Supplemental Form

PHS Fellowship Supplemental Form

OMB Number: 0925-0001

A. Application Type: From SF424 (R&R) Cover Page. The re	esponse provided on that page, regarding the type of application being submitted, is repeated here for your	reference as
you provide the responses that are appro	opriate for this Fellowship application. Renewal Continuation Revision	
B. Research Training Plan		
Introduction to Application (for RESUBMISSION applications only)	Add Attachment Delete Attachment	/iew Attachment
2. * Specific Aims	Add Attachment Delete Attachment	/iew Attachment
3. * Research Strategy	Add Attachment Delete Attachment V	/iew Attachment
 Progress Report Publication List (for RENEWAL applications only) 	Add Attachment Delete Attachment V	View Attachment
Human Subjects		
involvement of human subjects, is repeated	on from the Research & Related Other Project Information form. The response provided on that page, regarding seated here for your reference as you provide related responses for this Fellowship application. If you wish to please do so on the Research & Related Other Project Information form; you will not be able to edit the responsare Human Subjects Involved? Yes No	change
5. Human Subjects Involvement Indefinite?	Yes No	
6. Clinical Trial?	Yes No	
7. Agency-Defined Phase III Clinical Trial?	Yes No	
8. Protection of Human Subjects	Add Attachment Delete Attachment	View Attachment
9. Inclusion of Women and Minorities	Add Attachment Delete Attachment V	/iew Attachment
10. Inclusion of Children	Add Attachment Delete Attachment	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		
11. Vertebrate Animals Use Indefinite?	Yes No	
12. Vertebrate Animals	Add Attachment Delete Attachment	View Attachment
13. Select Agent Research Add Attachment Delete Attachment View Atta		View Attachment
14. Resource Sharing Plan Add Attachment Delete Attachm		View Attachment
15. * Respective Contributions Add Attachment Delete Attachment		View Attachment
16. * Selection of Sponsor and Institution	Add Attachment Delete Attachment	View Attachment
17. * Responsible Conduct of Research	Add Attachment Delete Attachment	View Attachment

PHS Fellowship Supplemental Form

C. Additional Information		
Human Embryonic Stem Cells		
1. * Does the proposed project involve human embryonic stem cells?		
If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/. 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: If "other", please Expected Completion Date indicate degree type: (month/year):		
Reset Entry		
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)		
Reset Entry Reset Entry		
Reset Entry		
Reset Entry		
6. * Applications for Concurrent Support? Yes No		
If yes, please describe in an attached file: Add Attachment Delete Attachment View Attachment		
7. * Goals for Fellowship Training and Career Add Attachment Delete Attachment View Attachment		
8. * Activities Planned Under This Award		
9. Doctoral Dissertation and Other Research Experience Add Attachment Delete Attachment View Attachment		
10. * Citizenship: U.S. Citizen or noncitizen national Permanent Resident of U.S. Pending		
Permanent Resident of U.S. (If a permanent resident of the U.S., a notarized statement must be provided by the time of award) Non-U.S. Citizen with temporary U.S. visa		

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) Form. Corrections to this field must be made in that form.

Field Name	Instructions
B. Research Training Plan	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.
	Research Training Plan Attachments
	(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)
	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.
	NIH and other PHS agencies require all text attachments to the SF424(R&R) application forms to be submitted as PDF files.
	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.
	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.
	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.
	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 pixels using 256 colors. Figures must be readable as printed on an 8.5 x 11 inch page at normal (100%) scale.
	Investigators must use image compression such as JPEG or PMG. Do not

Field Name	Instructions
	include figures or photographs as separate attachments either in the Appendix or elsewhere in the application.
	Separate Attachments
	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.
	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.
	Page Limitations
	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.
	Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html .
	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.
	Introduction – resubmissions and revisions only; limited to one page.
	• Specific Aims – limited to one page.
	Research Strategy – limited to six pages.
	Be succinct and remember that there is no requirement to use all six pages allotted to the Research Strategy.
	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).
	Unless otherwise specified in a PHS solicitation, Internet Web site addresses

Field Name	Instructions
	(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.
	Note: Begin each text section of the Research Training Plan with a section header (e.g., Introduction, Specific Aims, Research Strategy, etc.).
	Research Training Plan of Resubmission Applications
	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.
	Include sufficient information to permit an effective review without reviewers having to refer to any previous application.
1.	The Introduction (resubmissions only).
Introduction to Application (Resubmissi on Applications Only)	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.
	First time (new) applications should not include an Introduction unless specified in the FOA.
	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 .

Field Name	Instructions
2. Specific	Specific Aims are limited to one page.
Aims	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.
	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.
	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 .

Field Name	Instructions
3. Research	Research Strategy is limited to six pages.
Strategy	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).
	Follow the page limits for the Research Strategy in the table of page limits (<u>Table 2.6-1</u>), unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.
	a. Significance
	 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.
	b. Innovation
	 Fellowship applications should not include an Innovation section unless specified in the FOA.
	c. Approach
	 Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 14 (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.

Field Name	Instructions
	If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.
	If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.
	As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.
	Preliminary Studies for New Applications.
	For new applications, include information on preliminary studies, if any. Discuss the applicant's preliminary studies, data and/or experience pertinent to this application.
	When applicable, provide a succinct account of published and unpublished results, indicating progress toward their achievement.
	Progress Report for Renewal Applications.
	Renewal applications for individual fellowships are rare. You should consult with your program official before preparing such an application.
	In the rare instance that you are submitting a renewal application, provide a Progress Report. 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.
	A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in Item 5 (Progress Report Publication List); do not include that information here.
	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 .

Field Name	Instructions
4. Progress Report Publication List (for RENEWAL applications only)	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. 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 F. Appendix below).
Human Subjects	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. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

Field Name	Instructions
5. Human Subjects Involvement Indefinite?	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.
6. Clinical Trial	Check "Yes" or "No" to indicate whether the project includes a clinical trial.
7. Agency- Defined Phase III Clinical Trial?	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.
8. Protection of Human Subjects	Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan. 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. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy. 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.
9. Inclusion of Women and Minorities	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. Save this information in a single file in a location you remember. Click Add
	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 .

Field Name	Instructions
10. Inclusion of Children	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 Exemption 4, this section is required.
	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 .
Other Research Training Plan Sections	Consult with your Sponsor and Administrative Officials at the Sponsoring Institution before completing Items 11 through 17.
Are Vertebrate Animals Used?	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 11 and 12.
11. Vertebrate Animals Use Indefinite?	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.

Field Name	Instructions
12. Vertebrate	This section is required for applicants answering "Yes" to the question "Are vertebrate animals involved?" on the R&R Other Project Information form.
Animals	If Vertebrate Animals are involved in the project, address each of the five points below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the five required points below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. 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.
	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 below and verification of IACUC approval. If the grantee does not have an Animal Welfare Assurance, then an applicable Animal Welfare Assurance will be required (see Part III, Section 2.2 Vertebrate Animals for more information).
	The five points are as follows:
	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.
	 Provide information on the veterinary care of the animals involved. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
	5. Describe any method of euthanasia to be used and the 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.
	Do not use the vertebrate animal section to circumvent the page limits of the

Field Name	Instructions
	Research Strategy.
	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 .

Field Name	Instructions
13. Select Agent Research	Select agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist.pdf .
	If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, 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.selectagents.gov/SelectAgentsandToxinsExclusion s.html.
	S.Huin.
	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.
	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.
	1. Identify the select agent(s) to be used in the proposed research.
	2. Provide the registration status of all entities* where select agent(s) will be used.
	• If the performance site(s) is a foreign institution, provide the name (s) of the country or countries where select agent research will be performed.
	*An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."
	3. Provide a description of all facilities where the select agent(s) will be used.
	 Describe the procedures that will be used to monitor possession, use and transfer of select agent(s).
	 Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
	Describe the biocontainment resources available at all performance sites.

Field Name	Instructions
	If you are responding to a specific funding opportunity announcement, address any requirements specified by the FOA.
	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.
	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 .

Field Name	Instructions
14. Resource Sharing Plan (s)	NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Part III, 1.5 Sharing Research Resources. 1. Data Sharing Plan: 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. 2. Sharing Model Organisms: 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 (GDS): Applicants seeking funding for research that generates large-scale human or non-human genome data are expected to provide a plan for sharing of these data, or an appropriate explanation why sharing is not possible. Large-scale gen

Field Name	Instructions
15.	This item is limited to one page.
Respective Contribution s	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.
	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 .
16. Selection	This item is limited to one page.
of Sponsor and Institution	Describe the rationale/justification for the selection of the sponsor and institution.
	 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. 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. 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. 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.

Field Name	Instructions
17. Responsible	This item is limited to one page.
Conduct of Research	Note: An application will not be reviewed if it lacks this attachment.
	Provide an itemized plan for Instruction in the Responsible Conduct of Research (RCR) that addresses each of the five instruction components individually in the following order: 1) Format; 2) Subject Matter; 3) Faculty Participation; 4) Duration of Instruction; and 5) Frequency of Instruction.
	A sample RCR plan for fellowships is available at NIH Forms and Applications: http://grants.nih.gov/grants/funding/424/index.htm
	See Part III, 1.16 for additional information.
	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 .
C. Additional Information	
1. Human Embryonic Stem Cells	Indicate "Yes" if the proposed research involves human embryonic stem cells. See http://stemcells.nih.gov/info/basics/pages/basics3.aspx 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.
Fellowship Applicant	
2. Alternate Phone Number	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 SF424 (R&R) Form.
3. Degree Sought During Proposed Award	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.

Field Name	Instructions					
4. Field of Training for Current Proposal	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.)					
5. Current or Prior Kirschstein- NRSA Support?	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).					
	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 and other dual doctoral degree training (e.g., D.O./Ph.D., D.D.S./Ph.D., Au.D./Ph.D., and D.V.M./Ph.D.) programs allow for up to 6 years of predoctoral support).					
	Promptly report to the NIH IC to which this application is assigned any additional NRSA support received while this application is pending.					
6. Applications for Concurrent Support?	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.					
	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 .					

Field Name	Instructions						
7. Goals for	This item is limited to one page.						
Fellowship Training and Career	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.						
	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 .						
8. Activities	This item is limited to one page.						
Planned Under This Award	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. Include any courses that you plan to take to support the research training experience.						
	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.						
	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.						
9. Doctoral	This item is limited to two pages.						
Dissertation and	Summarize your research experience in chronological order.						
Research Experience	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.						
	In summarizing their research experience, Postdoctoral and Senior Fellowship applicants should include the areas studied and conclusions drawn.						
	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.						
	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 .						

Field Name	Instructions
10. Citizenship	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 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.
	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.
	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.
	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.
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.

Field Name	Instructions						
D. Sponsor	Sponsor and any Co-Sponsor(s) (if any) Information is limited to 6 pages.						
and Co- Sponsor Information	Create a heading at the top of the first page titled "Section IISponsor 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 cosponsor as well.						
	b. Sponsor's/Co-Sponsor's Previous Fellows/Trainees						
	Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to 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.						
E. Budget							

Field Name	Instructions
All Fellowship Applicants: 1. Tuition and Fees:	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 "Activities Planned Under This Award" of the Research Training Plan in Section B. If no tuition and fees are being requested, check the box provided. With the exception of senior fellowship applicants, no additional budget information is required. The final stipend and institutional allowance will be determined at the time of award. In accordance with NIH Guide NOT-OD-10-073, 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.
Senior Fellowship Applicants Only: 2. Present Institutional Base Salary:	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).
Senior Fellowship Applicants Only: 3. Stipend/ Salary During First Year of Proposed Fellowship:	 a. Federal Stipend Requested: Fellowship applicants must insert the stipend being requested for the initial period of support and the number of months. 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.

Field Name	Instructions					
F. Appendix	Only one copy of appendix material is necessary.					
	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.					
	Do not use the Appendix to circumvent the page limitations of the Research Strategy section of the Research Training Plan or any other section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html .					
	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 appendix requirements may be delayed in the review process.					
	New, resubmission, renewal, and revision applications may include the following materials in the Appendix:					
	• 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:					
	 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. 					
	Do not include unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication.					
	Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.					

Field Name	Instructions
	 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.
	Items that must not be included in the appendix:
	 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.
	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.

5.4 Letters of Reference (must be submitted electronically through 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 references may result in the application being returned to you without review.

Part A. Instructions for Fellowship Applicants:

Be sure to list the names of those individuals submitting Letters of Reference on your behalf in the SF424 (R&R) Form in the Cover Letter attachment.

Letters of Reference are an important part of the application for the Individual Fellowship Awards. Applicants must arrange to have at least three (and no more than five) references submitted on their behalf to the eRA Commons Web site at

https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new .

Letters of Reference are due by the application receipt deadline date. See NIH Guide Notice NOT-OD-11-079

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/co-sponsor of this application cannot be counted as a reference. The sponsor's/co-*

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. For postdoctoral applications, if not submitting a reference from your dissertation advisor or chief of service, provide an explanation in Item 12 – Other Attachments on the SF424 (R&R) Other Project Information Form. Also 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 (updated) Letters of Reference be submitted 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. Letters of Reference 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 Letters of Reference 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 Letters of Reference, applicants can monitor the submission of reference letters – though not access the actual documents through their eRA Commons Personal Profile. Failure to provide references may delay processing of your application or may result in the application being returned to you without review.

Once the letter has been submitted, confirmation e-mails will be sent to both the referee and the applicant following electronic submission. The confirmation sent to the applicant will include the referee's name and the date the letter was submitted. The confirmation sent to the referee will include the referee and applicant's names, a confirmation number, and the date the letter was submitted.

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

Applicants should provide the following instructions to their referees. Applicants can direct their referees to the Individual Fellowship Application Guide SF424 (R&R) at http://grants.nih.gov/grants/funding/424/index.htm, then go to Section 5.4, Part B. Instructions for Referees.

Part B. Instructions for Referees:

The fellowship applicant is applying to the NIH for an NRSA individual fellowship award. The purpose of this award is to provide support to promising applicants with the potential to become productive, independent investigators in scientific health-related research fields relevant to the missions of participating NIH Institutes and Centers.

Please put the name of the fellowship applicant at the top of the letter. Also, be sure to include your name and title in the letter.

Name of the fellowship applicant (First & Last Name as shown in the eRA Commons):	
Fellowship applicant's eRA Commons UserName:	
Funding Opportunity Announcement (FOA) Number:	

In two pages or less (PDF format), describe the qualities and potential of the fellowship applicant for the research training for which support is being requested (predoctoral, postdoctoral, or senior fellow). This should include your evaluation with special reference to:

- Research ability and potential to become an independent researcher
- · Adequacy of scientific and technical background
- Written and verbal communication abilities including ability to organize scientific data
- Quality of research endeavors or publications to date, if applicable
- Perseverance in pursuing goals
- Evidence of originality
- Need for further research experience and training
- Familiarity with research literature

Referees may provide any additional, related comments that they believe will help reviewers evaluate the merit of the candidate's application.

Letters of Reference must be submitted to the eRA Commons at https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new, and may be submitted any time after the Funding Opportunity Announcement opens and **not later than the application receipt due date.**

Failure to submit the required reference in the appropriate format may result in the application being returned to the applicant without review.

Submitting Reference Letters

Once you have accessed the letters of reference submission site (https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new), the following information must be entered before uploading the PDF reference letter attachment:

Referee Information:

- Referee First Name (Required)
- Referee Last Name (Required)
- Referee MI Name (middle initial) (Not Required)

- Referee E-mail (Required)
- Referee Institution/Affiliation (Required)
- Referee Department (Required)

Fellowship Application Information:

- 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 letter; not required otherwise)
- Fellowship Letter of Reference two pages maximum. Complete the letter 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://grants.nih.gov/grants/ElectronicReceipt/pdf guidelines.htm.

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

Revised letters of reference may be submitted prior to the application receipt deadline date.

- 5.5 (Reserved)
- 5.6 (Reserved)
- 5.7 (Reserved)

5.8 Planned Enrollment Report and Cumulative Inclusion Enrollment Report

NOTE: These report formats should NOT be used for collecting data from study participants. To ensure proper performance, please save frequently.

Please refer to <u>Part II (Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan)</u> for additional guidance on how and when to use the Planned Enrollment Report(s) and/or Cumulative Inclusion Enrollment Report(s).

5.8.1 Planned Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Domestic/Foreign:

Comments:

Planned Enrollment Report

OMB Number: 0925-0002

	Ethnic Categories						
Racial Categories	Not Hispan	ic or Latino	Hispanic	Total			
	Female	Male	Female	Male			
American Indian/ Alaska Native	0	0	0	0	0		
Asian	0	0	0	0	0		
Native Hawaiian or Other Pacific Islander	0	0	0	0	0		
Black or African American	0	0	0	0	0		
White	0	0	0	0	0		
More than One Race	0	0	0	0	0		
Total	0	0	0	0	0		

Study 1 of 1

To ensure proper performance, please save frequently.

Field Name	Instructions				
Study Title	Enter a unique title that describes the study that the participants will be involved in. If there is more than one study, provide a separate Study Title for each. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.				
Domestic/Foreign	Select whether the participants described in the planned enrollment report are domestic or foreign. At a minimum, domestic and foreign participants must be reported separately even if for the same study. This is a required field.				
Comments	Enter information you wish to provide about this planned enrollment report. This includes but is not limited to addressing information about distinctive subpopulations if relevant to the scientific hypotheses being studied and/or a study that will have a delayed onset. Maximum 500 characters.				
American Indian/Alaska Native	Enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino. These are required fields.				
Asian	Enter the expected number of females and males (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Asian and Hispanic or Latino. These are required fields.				
Native Hawaiian or Other Pacific Islander	Enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino. These are required fields.				
Black or African American	Enter the expected number of females and males (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; Enter the expected number of females and males (in the respective fields) who are Black or African American and Hispanic or Latino. These are required fields.				

Field Name	Instructions				
White	Enter the expected number of females and males (in the respective fields) who are White and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are White and Hispanic or Latino. These are required fields.				
More than One Race	Enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Hispanic or Latino. These are required fields.				
Total	The total fields at the bottom are auto-calculated to total all racial categories for females and males who are Not Hispanic or Latino and all racial categories for females and males who are Hispanic or Latino. The total fields at the right are auto-calculated to total all males and females of both Not Hispanic or Latino and Hispanic or Latino ethnicity in each racial category.				

5.8.2 Cumulative Inclusion Enrollment Report

Cumulative Inclusion Enrollment Report OMB Number: 0925-0002 This report format should NOT be used for collecting data from study participants.										
Study Title:										
Comments:										
					Ethnic C	ategories				
Basial Catanasia	Not	Hispanic or L		Hi	spanic or Lati		Unknown	/Not Reported		Total
Racial Categories	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Study 1 of 1

To ensure proper performance, please save frequently.

Field Name	Instructions
Study Title	Enter a unique title that describes the study that the participants will be involved in. The title should be the same as submitted on the original Planned Enrollment form for this study. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.
Comments	Enter information you wish to provide about this Cumulative Inclusion Enrollment Report. This includes but is not limited to information if distinctive subpopulations are relevant to the scientific hypotheses being studied. Maximum 500 characters.

Field Name	Instructions
American Indian/Alaska Native	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and of unknown/not reported ethnicity. These are required fields.
Asian	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and of unknown/not reported ethnicity. These are required fields.
Native Hawaiian or Other Pacific Islander	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and of unknown/not reported ethnicity. These are required fields.
Black or African American	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and of unknown/not reported ethnicity. These are required fields.

Field Name	Instructions
White	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and of unknown/not reported ethnicity. These are required fields.
More than One Race	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and of unknown/not reported ethnicity. These are required fields.
Unknown or Not Reported	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are of unknown/not reported race and of unknown/not reported ethnicity. These are required fields.
Total	The total fields at the bottom are auto-calculated to total all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino; all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Hispanic or Latino, and all racial categories for females, males, and individuals of unknown/not reported sex/gender who are of unknown/not reported ethnicity. The total fields at the right are auto-calculated to total all individuals in a given racial category.

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.

Letters of Reference are due by the application receipt deadline date. Although previously NIH provided a 5 business days grace period for the receipt of Letters of Reference after the application receipt due date, the new policy eliminates the grace period. 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.

6. The Peer Review Process

Overview

NIH policy is intended to ensure that applications for funding submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects" (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://grants.nih.gov/grants/peer review-process.htm.

Additional information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate Institute, Center, or Office.

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

Each FOA specifies all of the review criteria and considerations that will used in the evaluation of applications submitted for that FOA; RFAs and other types of funding opportunities (e.g., for construction or fellowship applications) may include different and/or additional review criteria and considerations. SRG members are instructed to evaluate research applications by addressing the scored review criteria (see below) and additional review criteria as applicable for the application.

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 score will reflect his/her evaluation of the potential overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer's scores given to each criterion. The final impact score for each discussed application will be determined by calculating

the arithmetic average of all the eligible members' impact scores, and multiplying the average by 10.

As part of the initial merit review, and regardless of whether an application is discussed or not discussed, all applicants will receive a written critique, called a Summary Statement. Unless stated otherwise in the FOA, the Summary Statement represents a combination of the reviewers' written comments and scores for individual criteria. The Summary Statement for discussed applications includes the Scientific Review Officer's summary of the members' discussion during the SRG meeting; the final impact 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 criteria will be reported individually on the Summary Statement. Final, numerical impact scores are not given for applications that are not discussed.

6.1 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?

<u>Institutional Environment and Commitment to Training:</u> 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.

<u>Protections for Human Subjects.</u> 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. For additional information, see the Human Subjects Protections Guidelines.

<u>Inclusion of Women, Minorities, and Children.</u> When the proposed project involves human subjects and/or NIH-defined research, the committee will evaluate the proposed plans for inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information, see the <u>Human Subjects Inclusion Guidelines</u>.

<u>Vertebrate Animals.</u> 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 the <u>Vertebrate Animals Checklist</u>.

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. All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant's career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) Format - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) Subject Matter - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) Faculty Participation - the role of the sponsor(s) and other faculty involvement in the fellow's instruction; 4) Duration of Instruction - the number of contact hours of instruction (at least eight contact hours are required); and 5) Frequency of Instruction –instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee. See also NOT-OD-10-019.

<u>Applications from Foreign Organizations</u>. 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.

<u>Select Agent Research.</u> 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) <u>Data Sharing Plan</u>; 2) <u>Sharing Model Organisms</u>; and 3) <u>Genomic Data Sharing (GDS) Plan</u>.

<u>Budget and Period of Support.</u> 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.